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Monday, February 10, 2014

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

5 CFR Part 6901

[Docket Number—2014–0001]

RIN 2700–AE03

Supplemental Standards of Ethical Conduct for Employees of the National Aeronautics and Space Administration

AGENCY: National Aeronautics and Space Administration.

ACTION: Interim Rule with request for comments; amendments.

SUMMARY: The National Aeronautics and Space Administration (NASA), with the concurrence of the Office of Government Ethics (OGE), is amending the Supplemental Standards of Ethical Conduct for Employees of the National Aeronautics and Space Administration. The interim rule will permit student interns to seek prior approval to engage in outside employment with a NASA contractor, subcontractor, grantee, or party to a NASA agreement in connection with work performed by that entity or under that agreement. These amendments will clarify the types of outside employment activities that require approval; streamline the process for approval; eliminate obsolete position titles; and extend the permissible time period of approval.

DATES: *Effective Date:* February 10, 2014. *Comment Date:* Comments must be received by April 11, 2014.

ADDRESSES: Comments must be identified with RINs 2700–AE03 and may be sent to NASA via the *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Please note that NASA will post all comments on the Internet with changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Adam F. Greenstone, Alternate Designated Agency Ethics Official, NASA Office of the General Counsel, 300 E. St. SW., Washington, DC 20546, 202.358.1775, *adam.f.greenstone@nasa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On August 7, 1992, OGE published the Standards of Ethical Conduct for Employees of the Executive Branch (OGE Standards). *See* 57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52483, and 60 FR 51167, with additional grace period extensions for certain existing provisions at 59 FR 4779–4780, 60 FR 6390–6391, and 60 FR 66857–66858. The OGE Standards, codified at 5 CFR part 2635, effective February 3, 1993, established uniform standards of ethical conduct that apply to all executive branch personnel. Section 2635.105 of the OGE Standards authorizes an agency, with the concurrence of OGE, to adopt agency-specific supplemental regulations that are necessary to properly implement its ethics program.

In 1994, NASA, with OGE's concurrence, established supplemental standards of ethical conduct for NASA employees. *See* 59 FR 49335–49338 (Sept. 28, 1994), as codified at 5 CFR part 6901. NASA, with OGE's concurrence, now amends its supplemental standards of conduct as follows.

Under the existing regulation at 5 CFR 6901.103(c), NASA employees other than special Government employees are generally prohibited from engaging in outside employment with a NASA contractor, subcontractor, or grantee in connection with work performed by that entity for NASA; or a party to a Space Act agreement, Commercial Launch Act agreement, or other agreement to which NASA is a party pursuant to specific statutory authority, if the employment is in connection with work performed under that agreement. When 5 CFR 6901.103 became effective in 1994, NASA stated that outside employment with those entities would cause reasonable persons to question the impartiality and objectivity with which NASA programs are administered. As a result, student interns generally have been barred from employment with an entity performing work under a NASA contract, grant, or Space Act agreement in connection with that work. Consequently, these students may not perform NASA-related work at their home institutions. This prohibition prevents a graduate assistant, for example, from performing basic research in connection with a NASA-funded research program.

NASA now has concluded that the prohibition is unnecessarily broad, and that the integrity of NASA's operations will not be diminished by liberalizing the current prohibition to permit student interns to seek approval to engage in outside activities with these entities. Student interns typically perform basic research functions without substantial involvement in NASA decisions that affect outside entities, and often spend extended periods in leave without pay status during semesters when they carry a full-time academic workload. It is also vital that students in STEM (science, technology, engineering, math) disciplines have full access to NASA development opportunities to maintain U.S. leadership in these fields. For these reasons, NASA, with OGE's concurrence, is retaining but liberalizing this provision in a revised paragraph (c) of § 6901.103 to permit management to approve such activities of student interns when NASA ethics officials determine that the activity would comply with Federal ethics laws and OGE regulations, to which employed student interns remain subject.

The interim rule makes a number of other minor revisions to clarify the rule and streamline the approval process. The interim rule tailors the approval requirement to engage in outside employment with an employee-owned business under § 6901.103(d)(3) to cases where the business performs or seeks to perform Federal government-related work. Likewise, the interim rule provides additional clarity to § 6901.103(d)(8) by describing the types of technical work that that would require approval.

Revised paragraph (g) of § 6901.103 streamlines the approval process by directing that employees must obtain approval from their supervisors. This revision provides efficiency by decentralizing the process for most career Senior Executive Service employees so that approval can be granted within their center, and

specifies the approval authority for certain other senior officials who may not obtain approval within their center. The revision provides that all requests must also undergo legal review prior to approval. For example, requests from Center Directors and Deputy Center Directors must be approved by the Associate Administrator at NASA Headquarters, with legal review by the Headquarters General Counsel's Office. Requests from NASA Chief Counsel at field centers must also be reviewed by the Headquarters General Counsel's Office.

Finally, revised paragraph (g)(4) extends the maximum time for which approval may be granted from three to five years to provide further administrative efficiency in cases where the reviewing offices consider a longer approval period to be appropriate.

Regulatory Analysis Section

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(a)(2), (b), and (d), good cause exists for waiving the regular notice of proposed rulemaking, opportunity for public comment, and 30-day delayed effective date for final rule amendment because this rule applies solely to agency personnel, organization, practice, and procedure; and relieves overly broad restrictions on NASA student interns performing work at their home academic institutions and approval requirements on certain employee outside activities NASA has determined are not needed. NASA has, however, decided to publish the amendments as an interim rule so that public comments may be considered prior to issuing a final rule. Accordingly, it is in the public interest that these revisions take effect as an interim rule upon the date of publication of this **Federal Register** rulemaking document, and in issuing a final rule on this matter NASA will consider written comments submitted by April 11, 2014.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule would not have a significant economic impact on a substantial number of small entities because this rule only pertains to NASA employees.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. This rule is not a significant regulatory action under section 3(f) of Executive order 12866, Regulatory Planning and Review, because this rule relates solely to the internal operations of NASA. Therefore, the Office of Management and Budget did not review this rule.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply to this rule because it does not contain any information collection requirement that requires approval of the Office of Management and Budget.

Small Business Regulatory Enforcement Fairness Act

This rule relates to agency management or personnel, and therefore the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) does not cover the interim rule.

Executive Order 13132, Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, Federalism, NASA has determined that the rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Unfunded Mandates Reform Act

For the purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this rule would not significantly or uniquely affect small governments and would not result in increased expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

List of Subjects in 5 CFR Part 6901

Ethical conduct.

For the reasons discussed in the preamble, NASA, with the concurrence of OGE, amends 5 CFR part 6901 as follows:

PART 6901—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

■ 1. The authority citation for part 6901 is revised to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 51 U.S.C. 20113(a); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403(a), 2635.802(a), 2635.803.

■ 2. Revise paragraphs (b), (c), (d), (e), (f), and (g) of § 6901.103 to read as follows:

§ 6901.103 Outside employment.

* * * * *

(b) *Definitions.* Unless a term is otherwise defined in this part, the definitions set forth in 5 CFR part 2635 apply to terms used in this section. In addition, for purposes of this section:

(1) *Outside employment* means any form of compensated or uncompensated non-Federal employment or business relationship involving the provision of personal services by the employee. It includes, but is not limited to, personal services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, trustee, teacher, or speaker. It includes writing when done under an arrangement with another person for production or publication of the written product. It does not, however, include participation in the activities of a nonprofit charitable, religious, professional, social, fraternal, educational, recreational, public service, or civic organization, unless the organization is a prohibited source or unless such activities involve the provision of professional services or advice, or are for compensation other than reimbursement of expenses.

(2) *Profession* has the meaning set forth in 5 CFR 2636.305(b)(1).

(3) *Student intern* means a student employed through a student internship program implemented by the Office of Personnel Management (OPM).

(c) *Prohibited outside employment.* A NASA employee, other than a special Government employee or a student intern, shall not engage in outside employment with the following:

(1) A NASA contractor, subcontractor, or grantee in connection with work performed by that entity for NASA; or

(2) A party to a Space Act agreement, Commercial Launch Act agreement, or other agreement to which NASA is a party pursuant to specific statutory authority, if the employment is in

connection with work performed under that agreement.

(d) *Prior approval for outside employment.* A NASA employee, other than a special Government employee, shall request and obtain approval before engaging in the following outside employment activities:

(1) Teaching, speaking, writing, or editing, unless the subject matter pertains to the private interests of the employee, such as a hobby, cultural activity, or a professional pursuit unrelated to the employee's official duties;

(2) The practice of a profession or the rendering of professional consulting services;

(3) The management or conduct of a business in which the employee or the employee's spouse has an ownership interest, if that business performs, or may seek to perform, work (other than routine consumer transactions) for the Federal Government or for a NASA contractor, grantee, or other party to an agreement with NASA;

(4) Holding State or local public office, whether by election or appointment;

(5) Employment with a NASA contractor, subcontractor, or grantee;

(6) Employment with a party to a Space Act agreement, Commercial Launch Act agreement, or other agreement to which NASA is a party pursuant to specific statutory authority;

(7) Serving as an officer, trustee, or member of a board, directorate, or other such body of a for profit organization or of a nonprofit organization that is a prohibited source; or

(8) Employment which involves the practice of a NASA-owned invention or the performance of experimental, developmental, research, design, or engineering work that relates to the official duties of such employee.

(e) *Prior approval requested by employee.* Even when not required by paragraph (d) of this section, a NASA employee may request prior approval using the procedures set forth in this section.

(f) *Form of request for approval.* A request for approval of outside employment shall be in writing and shall include the following:

(1) The employee's name and occupational title;

(2) The nature of the employment, including a full description of the specific duties or services to be performed and a statement explaining any relationship between the outside activity and the official duties of the employee;

(3) The name and address of the person or organization for which work will be done;

(4) The estimated total time that will be devoted to the activity. If the employment is on a continuing basis, indicate the estimated number of hours per year; for other employment, indicate the anticipated beginning and ending date;

(5) A statement as to whether the work can be performed entirely outside of the employee's regular duty hours and, if not, the estimated number of hours of absence from work that will be required;

(6) Whether the employee will receive compensation for the outside activity, and, if the employee is a covered noncareer employee as defined by 5 CFR 2636.303, the amount of compensation to be received; and

(7) A statement that the employee currently has no official duties involving a matter that affects the outside employer and will disqualify from future participation in matters that could directly affect the outside employer.

(g) *Approval of requests*— (1) When required to obtain approval prior to commencing outside employment pursuant to paragraph (d) of this section, a NASA employee shall receive approval from the employee's immediate supervisor. Additional authority to approve requests is as follows:

(i) Center Directors and Deputy Center Directors shall receive approval by the Associate Administrator;

(ii) Center employees shall receive approval from the Center Director or a person designated to act for the Center Director; and

(iii) Headquarters employees shall receive approval from the employee's Official-in-Charge.

(2) Prior to approval, the Office of the General Counsel shall review requests by Headquarters employees, Center Directors, Deputy Center Directors, and Center Chief Counsel. All other requests shall be reviewed by the Center Chief Counsel's office, and for Office of Inspector General employees, by the Counsel to the Inspector General.

(3) *Standard for approval.* Approval will be granted unless a determination is made that the prospective outside employment is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

(4) *Scope of approval.* Approval will be for a period not to exceed five years. Upon a significant change in the nature or scope of the outside employment or in the employee's NASA position, the employee shall submit a revised request for approval.

(5) *Notification of approval or disapproval.* Employees will be notified in writing of the action taken on their requests.

(6) *Records of requests.* All requests for approval will be maintained in the local human resources/personnel office where the requesting employee works, or alternatively by the local NASA legal office upon the determination of the Center Chief Counsel and by the Office of the General Counsel upon the determination of the General Counsel.

Charles F. Bolden Jr.,

Administrator, National Aeronautics and Space Administration.

Walter M. Shaub, Jr.,

Director, United States Office of Government Ethics.

[FR Doc. 2014–02212 Filed 2–7–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2009–0094]

RIN 0579–AD45

Importation of Live Birds and Poultry, Poultry Meat, and Poultry Products From a Region in the European Union; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: In a final rule published in the **Federal Register** on March 29, 2013, and effective on April 15, 2013, we amended the regulations governing the importation of animals and animal products by recognizing 25 Member States of the European Union (EU) as the Animal and Plant Health Inspection Service (APHIS)-defined EU Poultry Trade Region. In that rule, we established requirements for the importation of live birds and poultry, and poultry meat and products, from the APHIS-defined EU Poultry Trade Region. In the final rule, it was not our intent to prohibit the importation of birds, poultry, and poultry meat and products from Member States of the APHIS-defined EU Poultry Trade Region that conduct trade in poultry and poultry products with other regions that APHIS recognizes as being free of Newcastle disease and highly

pathogenic avian influenza. It was also not our intent that the import requirements for cooked poultry meat and products from the APHIS-defined EU Poultry Trade Region not be equivalent with the requirements we apply to other regions whenever an outbreak of Newcastle disease or highly pathogenic avian influenza occurs in those regions. This document amends the regulations to reflect our original intentions.

DATES: Effective Date: February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Case Manager, Regionalization and Evaluation, National Import Export Services, Veterinary Services, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737–1231; (301) 851–3300.

SUPPLEMENTARY INFORMATION: In a final rule[1] that was published in the **Federal Register** on March 29, 2013 (78 FR 19080–19085, Docket No. APHIS–2009–0094), and effective on April 15, 2013, we amended the regulations governing the importation of animals and animal products by recognizing 25 Member States of the European Union (EU) as the Animal and Plant Health Inspection Service (APHIS)-defined EU Poultry Trade Region.

The rule was based on our determination that the region meets our requirements for being considered free of Newcastle disease and highly pathogenic avian influenza (HPAI) and established requirements for the importation of live birds and poultry, and poultry meat and products, from the APHIS-defined EU Poultry Trade Region.

As published, § 94.28(a)(3) requires that live birds and poultry from which poultry meat and products are derived and intended for export to the United States must only originate from within the APHIS-defined EU Poultry Trade Region, and that the farms of origin must not have received live birds or poultry imported from outside the APHIS-defined EU Poultry Trade Region. Similarly, § 94.28(b)(3) requires that live birds and poultry intended for export to the United States must only originate from within the APHIS-defined EU Poultry Trade Region and that the farms of origin must not have received birds or poultry imported from outside the APHIS-defined EU Poultry Trade Region.

These import requirements are not consistent with how we regulate poultry imports from other countries and regions that we recognize as being free of Newcastle disease and HPAI. We allow such regions to import live birds and poultry, and poultry meat and products, from other regions that are also free of those diseases, and we intended the APHIS-defined EU Poultry Trade Region to be able to do likewise.

Therefore, in keeping with our original intention, we are removing paragraphs (a)(3) and (b)(3) in § 94.28. Paragraph § 94.28(a)(5) will be redesignated as § 94.28(a)(4) and paragraph § 94.28(b)(5) will be redesignated as § 94.28(b)(4). References to these paragraphs in paragraphs (c) and (d) of § 94.28 will be amended to reflect these changes. As a result, farms within the APHIS-defined EU Poultry Trade Region will be able to export to the United States live birds and poultry originating from outside their region, as well as poultry meat and products that were derived from poultry originating from outside their region.

However, § 94.28(a)(1) and (b)(1) will continue to require that live birds and poultry, and poultry meat and products, must not have been from regions or zones in which Newcastle disease or HPAI are considered to exist. Likewise, paragraphs (a)(2) and (b)(2) of § 94.28 will continue to require that prior to export to the United States, live birds and poultry, and poultry meat and products, are not commingled with live birds and poultry, or poultry meat and products, from regions where Newcastle disease or HPAI are considered to exist. Additionally, live birds and poultry, and poultry meat and products, imported from the APHIS-defined EU Poultry Trade Region must be accompanied by a certificate indicating the zone of origin within that region. This requirement ensures they do not originate from restricted zones imposed within the APHIS-defined EU Poultry Trade Region due to outbreaks of Newcastle disease or HPAI.

In addition, we intended that the import requirements for cooked poultry meat and products from the APHIS-defined EU Poultry Trade Region be equivalent with the requirements we apply to other regions whenever an outbreak of Newcastle disease or HPAI occurs in those regions. Therefore, we are amending § 94.28(a)(1) by adding a statement that poultry meat and products are also allowed to be imported to the United States from the APHIS-defined EU Poultry Trade Region if accompanied by a certificate specifying that the articles were cooked and processed in accordance with the regulations in § 94.6(b)(3) or (b)(4).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 94.28 is amended as follows:

■ a. By revising the introductory text of paragraph (a)(1);

■ b. By removing paragraph (a)(3) and redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(3) and (a)(4), respectively;

■ c. In newly designated paragraph (a)(4), by removing the reference "(a)(4)" and adding the reference "(a)(3)" in its place;

■ d. By removing paragraph (b)(3) and redesignating paragraphs (b)(4) and (b)(5) as paragraphs (b)(3) and (b)(4), respectively;

■ e. In newly designated paragraph (b)(4), by removing the reference "(b)(4)" and adding the reference "(b)(3)" in its place;

■ f. By withdrawing the amendment to paragraph (c) published December 4, 2013 (78 FR 73001);

■ g. In paragraph (c), by removing the citation "§ 94.28(b)(5)" and adding "paragraph (b)(4) of this section" in its place; and

■ h. In paragraph (d), by removing the references "(a)(5)" and "(b)(5)" and adding the references "(a)(4)" and "(b)(4)" in their place, respectively.

The revision reads as follows:

§ 94.28 Restrictions on the importation of poultry meat and products, and live birds and poultry, from the APHIS-defined EU Poultry Trade Region.

(a) * * *

(1) The poultry meat and products must not have been derived from birds and poultry that were in any of the following regions or zones, unless the birds and poultry were slaughtered after the periods described, or unless the poultry meat and products are

[1] To view the rule, supporting analyses, and comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0094.*

accompanied by a certificate specifying that the articles were cooked and processed in accordance with the regulations in § 94.6(b)(3) or (b)(4):

* * * * *

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02768 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1071

[Docket No: CFPB–2012–0020]

RIN 3170–AA27

Equal Access to Justice Act Implementation Rule

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: On June 29, 2012, the Consumer Financial Protection Bureau (Bureau) published in the **Federal Register** an interim final rule implementing the Equal Access to Justice Act (EAJA or the Act). EAJA requires agencies that conduct adversary adjudications to award attorney fees and other litigation expenses to certain parties other than the United States in certain circumstances. EAJA also requires agencies that conduct adversary adjudications to establish procedures for the submission and consideration of applications for the award of fees and other expenses. After reviewing and considering the single public comment offered on its interim final rule, the Bureau adopts the interim final rule without change.

DATES: This final rule is effective on March 12, 2014.

FOR FURTHER INFORMATION CONTACT: John R. Coleman, Senior Counsel, Legal Division, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552; (202) 435–7254.

SUPPLEMENTARY INFORMATION:

I. Background

Originally enacted in 1980, EAJA provides that "[a]n agency that conducts an adversary adjudication shall award, to a prevailing party other than the United States, fees and other expenses incurred by that party in connection with that proceeding, unless the adjudicative officer of the agency finds that the position of the agency was substantially justified or that special circumstances make an award unjust." 5 U.S.C. 504(a)(1). The Administrative Conference of the United States (ACUS) was charged with coordination of the procedural rules adopted by various agencies to implement EAJA. To carry out this responsibility, ACUS issued model rules implementing EAJA (46 FR 32900, June 25, 1981), after receiving public comment on draft model rules (46 FR 15895, March 10, 1981). ACUS published revised model rules in 1986 that reflected the amendments Congress made when it re-authorized the Act in 1985. 51 FR 16659 (May 6, 1986), previously codified at 1 CFR part 315 (1995); *see* Administrative Conference of the U.S., Federal Administrative Procedure Sourcebook at 419 (2d ed. 1992). ACUS did not publish model rules reflecting amendments to the Act made since 1985 before ACUS was temporarily defunded in 1996.

When drafting the interim final rule, the Bureau used the 1986 ACUS model rules as a point of departure, modifying them to put them in plain language, to reflect more recent amendments to the Act, and to make certain changes the Bureau believed were warranted for reasons explained in the section-by-section analysis published with the interim final rule.

On June 29, 2012, the Bureau published its interim final rule implementing EAJA with a request for comment. 77 FR 39117. The interim final rule described each section of the rule and explained the basis of the rule with reference to the ACUS model rules, or those of other agencies, as appropriate. The comment period on the interim final rule ended on August 28, 2012. After reviewing and considering the single public comment offered, the Bureau is now promulgating its final rule implementing EAJA.

II. Legal Authority

The Bureau promulgates the final rule pursuant to 5 U.S.C. 504(c)(1).

III. Public Comment on the Interim Final Rule

In response to the interim final rule, the Bureau received one letter from an individual consumer. The comment letter from the consumer did not contain any specific comments or suggestions pertaining to the interim final rule. Accordingly, the Bureau is adopting the interim final rule without change.

IV. Regulatory Requirements

As noted in publishing the Interim Final Rule, under the Administrative Procedure Act, 5 U.S.C. 553(b), notice and comment is not required for rules of agency organization, procedure, or practice. As discussed in the preamble to the Interim Final Rule, the Bureau confirms its finding that this is a procedural rule for which notice and comment is not required. Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a).

V. Paperwork Reduction Act

According to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) the Bureau may not conduct or sponsor a collection of information as defined by the PRA and, notwithstanding any other provisions of law, persons are not required to respond to a collection of information unless it displays a current valid Office of Management and Budget (OMB) control number. The collections of information contained in this rule, and identified as such, have been approved by OMB and assigned the control number 3170–0040.

A. Information Collection Requirements

EAJA provides for payment of fees and expenses to eligible parties who have prevailed against the Bureau in certain administrative proceedings. In order to obtain an award, the statute and associated regulations (12 CFR part 1071) require the filing of an application that shows that the party is a prevailing party and is eligible to receive an award under the Act. The Bureau regulations implementing the EAJA require applicants to submit certain information in their applications, as detailed in 12 CFR part 1071, subparts B, C. The Bureau estimates that as many as 3 applications may be filed annually with the Bureau and that it will take on average about 5 hours to complete and file an application for an award in accordance with the requirements of 12 CFR part 1071, subparts B, C, for a total estimated annual burden of 15 hours.

B. Comments

The Bureau published a 60-day **Federal Register** notice on August 23, 2013 (78 FR 52513). Comments were solicited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information shall have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. The Bureau received no comments in response to this notice. The Bureau has a continuing interest in the public's opinions of its collections of information. At any time, comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, may be sent to the Bureau at the Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, or by the Internet to *CFPB_Public_PRA@cfpb.gov.*

List of Subjects in 12 CFR Part 1071

Administrative practice and procedure, Banks, Banking, Consumer protection, Credit, Credit unions, Equal access to justice, Law enforcement, National banks, Savings associations.

Authority and Issuance

Accordingly, for the reasons set forth above, under the authority of 5 U.S.C. 504, the interim final rule establishing 12 CFR part 1071 published at 77 FR 39117, June 29, 2012, is adopted as a final rule without change.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2014–02115 Filed 2–7–14; 8:45 am]

BILLING CODE 4810–AM–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 240 and 260

[Release Nos. 33–9545; 34–71482; 39–2495; File No. S7–26–11]

RIN 3235–AL17

Extension of Exemptions for Security-Based Swaps

AGENCY: Securities and Exchange Commission.

ACTION: Interim final rule; extension.

SUMMARY: We are adopting amendments to the expiration dates in our interim final rules that provide exemptions under the Securities Act of 1933, the Securities Exchange Act of 1934, and the Trust Indenture Act of 1939 for those security-based swaps that prior to July 16, 2011 were security-based swap agreements and are defined as "securities" under the Securities Act and the Exchange Act as of July 16, 2011 due solely to the provisions of Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Under the amendments, the expiration dates in the interim final rules will be extended to February 11, 2017. If we adopt further rules relating to issues raised by the application of the Securities Act or the other federal securities laws to security-based swaps before February 11, 2017, we may determine to alter the expiration dates in the interim final rules as part of that rulemaking.

DATES: The amendments are effective February 10, 2014. See Section I of the **SUPPLEMENTARY INFORMATION** concerning amendment of expiration dates in the interim final rules.

FOR FURTHER INFORMATION CONTACT: Andrew Schoeffler, Special Counsel, Office of Capital Markets Trends, Division of Corporation Finance, at (202) 551–3860, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: We are adopting amendments to the following rules: interim final Rule 240 under the Securities Act of 1933 ("Securities Act"),[1] interim final Rules 12a–11 and 12h–1(i) under the Securities Exchange Act of 1934 ("Exchange Act"),[2] and interim final Rule 4d–12 under the Trust Indenture Act of 1939 ("Trust Indenture Act").[3]

I. Amendment of Expiration Dates in the Interim Final Rules

A. Background Regarding the Adoption of the Interim Final Rules

In July 2011, we adopted interim final Rule 240 under the Securities Act, interim final Rules 12a–11 and 12h–1(i) under the Exchange Act, and interim final Rule 4d–12 under the Trust Indenture Act (collectively, the "interim final rules").[4] The interim final rules provide exemptions under the Securities Act, the Exchange Act, and the Trust Indenture Act for those security-based swaps that prior to July 16, 2011 ("Title VII effective date") were "security-based swap agreements" and are defined as "securities" under the Securities Act and the Exchange Act as of the Title VII effective date due solely to the provisions of Title VII of the Dodd-Frank Act.[5] The interim final rules exempt offers and sales of security-based swap agreements that became security-based swaps on the Title VII effective date from all provisions of the Securities Act, other than the Section 17(a) anti-fraud provisions, as well as from the Exchange Act registration requirements and from the provisions of the Trust Indenture Act,[6] provided certain conditions are met.[7] In February 2013, we adopted amendments to the interim final rules to extend the expiration dates in the interim final rules from February 11, 2013 to February 11, 2014.[8]

Title VII amended the Securities Act and the Exchange Act to include "security-based swaps" in the definition of "security" for purposes of those statutes.[9] As a result, "security-based swaps" became subject to the provisions of the Securities Act and the Exchange Act and the rules and regulations thereunder applicable to "securities."[10]

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[1] 15 U.S.C. 77a *et seq.*

[2] 15 U.S.C. 78a *et seq.*

[3] 15 U.S.C. 77aaa *et seq.*

[4] *See* 17 CFR 230.240, 17 CFR 240.12a–11, 17 CFR 240.12h–1, and 17 CFR 260.4d–12. *See also Exemptions for Security-Based Swaps,* Release No. 33–9231 (Jul. 1, 2011), 76 FR 40605 (Jul. 11, 2011) ("Interim Final Rules Adopting Release").

[5] The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010). The provisions of Title VII generally were effective on July 16, 2011 (360 days after enactment of the Dodd-Frank Act), unless a provision requires a rulemaking. If a Title VII provision requires a rulemaking, it will go into effect "not less than" 60 days after publication of the related final rule or on July 16, 2011, whichever is later. *See* Section 774 of the Dodd-Frank Act.

[6] The category of security-based swaps covered by the interim final rules involves those that would have been defined as "security-based swap agreements" prior to the enactment of Title VII. That definition of "security-based swap agreement" does not include security-based swaps that are based on or reference only loans and indexes only of loans. The Division of Corporation Finance issued a no-action letter that addressed the availability of the interim final rules to offers and sales of security-based swaps that are based on or reference only loans or indexes only of loans. *See* Cleary Gottlieb Steen & Hamilton LLP (Jul. 15, 2011) ("Cleary Gottlieb No-Action Letter"). The Cleary Gottlieb No-Action Letter will remain in effect for so long as the interim final rules remain in effect.

[7] The security-based swap that is exempt must be a security-based swap agreement (as defined prior to the Title VII effective date) and entered into between eligible contract participants (as defined prior to the Title VII effective date). *See* Rule 240 under the Securities Act [17 CFR 230.240]. *See also* Interim Final Rules Adopting Release.

[8] *See Extension of Exemptions for Security-Based Swaps,* Release No. 33–9383 (Jan. 29, 2013), 78 FR 7654 (Feb. 4, 2013).

[9] *See* Sections 761(a)(2) and 768(a)(1) of the Dodd-Frank Act (amending Section 3(a)(10) of the Exchange Act [15 U.S.C. 78c(a)(10)] and Section 2(a)(1) of the Securities Act [15 U.S.C. 77b(a)(1)], respectively).

[10] The Securities Act requires that any offer and sale of a security must be either registered under the Securities Act or made pursuant to an exemption from registration. *See* Section 5 of the Securities Act [15 U.S.C. 77e]. In addition, certain provisions of the Exchange Act relating to the registration of classes of securities and the indenture qualification provisions of the Trust Indenture Act of 1939 ("Trust Indenture Act") [15 U.S.C. 77aaa *et seq.*] also potentially could apply to security-based swaps. The provisions of Section 12 of the Exchange Act could, without an exemption, require that security-based swaps be registered before a transaction could be effected on a national securities exchange. *See* Section 12(a) of the Exchange Act [15 U.S.C. 78l(a)]. In addition, registration of a class of security-based swaps under Section 12(g) of the Exchange Act could be required

The interim final rules were intended to allow security-based swap agreements that became security-based swaps on the Title VII effective date to continue to trade as they did prior to the enactment of Title VII.[11] We were concerned about disrupting the operation of the security-based swaps market until the compliance date for final rules that we may adopt further defining the terms "security-based swap" and "eligible contract participant."[12] We recognized that until we further defined such terms, market participants may be uncertain as to how to comply with the registration requirements of the Securities Act applicable to securities transactions, the registration requirements of the Exchange Act applicable to classes of securities, and the indenture provisions of the Trust Indenture Act.[13]

We also needed additional time and market input to evaluate the implications under the Securities Act, the Exchange Act, and the Trust Indenture Act of including the term "security-based swap" in the definition of "security."[14] We understood from market participants that there were several types of trading platforms being used to effect transactions in security-based swaps, including security-based swap agreements that became security-based swaps on the Title VII effective date, that would likely register as security-based swap execution facilities ("security-based SEFs")[15] and that the use of trading platforms to effect security-based swap transactions would continue after the Title VII effective date.[16] We also understood from market participants that if parties continued to engage in the same type of trading activities after the Title VII effective date that they were engaging in prior to the Title VII effective date with respect to security-based swap agreements that became security-based swaps on the Title VII effective date, such activities could raise concerns about the availability of exemptions from the registration requirements of the Securities Act and the Exchange Act.[17] The interim final rules thus allow market participants to continue to use trading platforms to publish quotes for security-based swaps and enter into transactions involving security-based swaps that are the subject of individual negotiation without concern that such activities may not comply with the applicable provisions of the federal securities laws.[18]

B. Comments Received on the Interim Final Rules

At the time of adoption of the interim final rules in July 2011, we requested comment on various aspects of the interim final rules. In particular, we requested comment on the following:[19] (i) Whether security-based swaps are transacted or expected to be transacted following the full implementation of Title VII in a manner that would not permit the parties to rely on existing exemptions under the Securities Act and the Exchange Act; and (ii) whether we should consider additional exemptions under the Securities Act and the Exchange Act for security-based swaps traded on a national securities exchange or through a security-based SEF with eligible contract participants.[20]

We received letters from three commenters regarding the interim final rules.[21] One commenter opposed any exemptions for security-based swaps, including the exemptions provided in the interim final rules, but did not provide any explanation for the reason.[22] The two other commenters supported the interim final rules.[23] These commenters stated their view that the interim final rules were necessary and appropriate steps to prevent disruption of the security-based swaps market and to ensure the orderly implementation of Title VII.[24] These commenters provided a description of the security-based swaps market as it currently functions and how it may

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if the security-based swap is considered an equity security and held of record by either 2000 persons or 500 persons who are not accredited investors at the end of a fiscal year. *See* Section 12(g)(1)(A) of the Exchange Act [15 U.S.C. 78l(g)(1)(A)]. Further, without an exemption, the Trust Indenture Act could require qualification of an indenture for security-based swaps considered to be debt. *See* 15 U.S.C. 77aaa *et seq.*

[11] *See* Interim Final Rules Adopting Release.

[12] *Id.*

[13] *Id. See also* footnote 10 above.

[14] *Id.* Prior to the Title VII effective date, security-based swap agreements that became security-based swaps on the Title VII effective date were outside the scope of the federal securities laws, other than the anti-fraud and certain other provisions. *See* Section 2A of the Securities Act [15 U.S.C. 77b(b)–1)] and Section 3A of the Exchange Act [15 U.S.C. 78c–1], each as in effect prior to the Title VII effective date.

[15] A security-based swap execution facility is a trading system or platform in which multiple participants have the ability to execute or trade security-based swaps by accepting bids and offers made by multiple participants in the facility or system, through any means of interstate commerce, including any trading facility, that facilitates the execution of security-based swaps between persons and is not a national securities exchange. *See* Section 3(a)(77) of the Exchange Act [15 U.S.C. 78c(a)(77)]. *See also* Section 3D of the Exchange Act [15 U.S.C. 78c–4] and *Registration and Regulation of Security-Based Swap Execution Facilities,* Release No. 34–63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011) ("Security-Based SEF Proposing Release").

[16] *See* Interim Final Rules Adopting Release.

[17] *Id.* We received comments expressing concern regarding the implications of including security-based swaps in the definition of "security." Commenters indicated that they were still analyzing the full implications of such expansion of the definition of "security" and that it would take time. Market participants requested temporary relief from certain provisions of the Securities Act and the Exchange Act so that parties could complete their analysis and submit requests for more targeted relief. *Id.*

[18] The interim final rules do not cover security-based swaps that are not subject to individual negotiation. The interim final rules apply only with respect to a security-based swap that would have been a security-based swap agreement under the definition of that term prior to the Title VII effective date. That definition incorporated the definition of "swap agreement," which required that the agreement, contract or transaction be "subject to individual negotiation." *See* Interim Final Rules Adopting Release.

[19] *Id.* We also requested comment on these matters in an earlier proposing release regarding exemptions for security-based swap transactions involving an eligible clearing agency. *See Exemptions For Security-Based Swaps Issued By Certain Clearing Agencies,* Release No. 33–9222 (Jun. 9, 2011), 76 FR 34920 (Jun. 15, 2011) ("Cleared SBS Exemptions Proposing Release").

[20] The term "eligible contract participant" is defined in Section 1a(18) of the Commodity Exchange Act [7 U.S.C. 1a(18)]. The definitions of the term "eligible contract participant" in the Securities Act and the Exchange Act both refer to the definition of "eligible contract participant" in the Commodity Exchange Act. *See* Section 5(e) of the Securities Act [15 U.S.C. 77e(e)] and Section 3(a)(65) of the Exchange Act [15 U.S.C. 78c(a)(65)]. The eligible contract participant definition includes several categories of persons: Financial institutions; insurance companies; investment companies; commodity pools; business entities, such as corporations, partnerships, and trusts; employee benefit plans; government entities, such as the United States, a State or local municipality, a foreign government, a multinational or supranational government entity, or an instrumentality, agency or department of such entities; market professionals, such as broker dealers, futures commission merchants, floor brokers, and investment advisors; and natural persons with a specified dollar amount invested on a discretionary basis. The Commission and the Commodity Futures Trading Commission ("CFTC") adopted final rules further defining the term "eligible contract participant." The CFTC staff issued a letter, Staff Interpretations and No-Action Relief Regarding ECP Status: Swap Guarantee Arrangements; Jointly and Severally Liable Counterparties; Amounts Invested on a Discretionary Basis; and "Anticipatory ECPs," CFTC Letter No. 12–17 (Oct. 12, 2012). Such letter does not interpret or further define the term "eligible contract participant" for purposes of Section 712(d) of the Dodd-Frank Act or the federal securities laws. *See Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant" and "Eligible Contract Participant",* Release No. 34–66868 (Apr. 27, 2012), 77 FR 30596 (May 23, 2012) ("Intermediary Definitions Adopting Release").

[21] *See* letter from Kenneth E. Bentsen, Jr., Executive Vice President, Public Policy and Advocacy, The Securities Industry and Financial Markets Association ("SIFMA"), dated December 21, 2012 ("SIFMA Letter"); letter from Kenneth E. Bentsen, Jr., Executive Vice President, Public Policy and Advocacy, SIFMA, and Robert Pickel, Chief Executive Officer, International Swaps and Derivatives Association ("ISDA"), dated Apr. 20, 2012 ("SIFMA/ISDA Letter"); and letter from Tom Nappi, dated Jul. 14, 2011 ("Nappi Letter").

[22] *See* Nappi Letter.

[23] *See* SIFMA Letter and SIFMA/ISDA Letter.

[24] *See* SIFMA/ISDA Letter.

function following the full implementation of Title VII.[25] These commenters expressed concerns about the availability of exemptions from the registration requirements of the Securities Act for security-based swap transactions entered into solely between eligible contract participants due to the operation of security-based swap trading platforms and the publication or distribution of other information regarding security-based swaps.[26] They indicated that certain communications involving security-based swaps, such as the publication or distribution of price quotes, may be available on or through trading platforms on an unrestricted basis, including following the full implementation of Title VII.[27] They also indicated that security-based swap dealers publish and distribute communications they characterized as research regarding security-based swap transactions that may be broadly disseminated and could be available on an unrestricted basis.[28] They were concerned that unrestricted access to these communications could affect the availability of exemptions from the registration requirements of the Securities Act, such as the exemption in Section 4(a)(2), for security-based swap transactions entered into solely between eligible contract participants.[29] Based on their concerns regarding the availability of exemptions from the registration requirements of the Securities Act, these commenters requested that we adopt permanent relief from the registration requirements of Section 5 of the Securities Act for offers and sales of security-based swaps[30] solely between eligible contract participants.[31] These commenters also requested relief under the Exchange Act for offers and sales of security-based swaps solely between eligible contract participants.[32] They were concerned that ambiguity regarding the definition of a "class" as applied to security-based swaps could raise concerns about the registration requirements of Section 12(g) of the Exchange Act.[33] Finally, these commenters requested relief from Section 304(d) of the Trust Indenture Act for security-based swaps entered into solely between eligible contract participants.[34] They believed that the protections of the Trust Indenture Act are not necessary for these transactions because they involve contracts between two counterparties who are capable of enforcing obligations under the security-based swaps directly.[35]

Moreover, although not submitted in connection with the interim final rules, we received two comment letters from four commenters regarding the exemptions for security-based swap transactions involving an eligible clearing agency.[36] These letters discussed issues arising with respect to security-based swap transactions not involving an eligible clearing agency and requested exemptions under the Securities Act, the Exchange Act, and the Trust Indenture Act for security-based swap transactions entered into between eligible contract participants.[37] In adopting the exemptions for security-based swap transactions involving an eligible clearing agency, we indicated that these commenters' suggestions were more appropriate to be considered in connection with the interim final rules.[38]

We subsequently extended the expiration dates in the interim final rules from February 11, 2013 to February 11, 2014 to enable us to continue our evaluation of the implications for security-based swaps as securities and determine whether other regulatory action is appropriate before the expiration date of the interim final rules.[39] We indicated at that time that we were carefully considering the comments we had received on the interim final rules as part of our evaluation of the implications for security-based swaps resulting from the inclusion of the term "security-based swap" in the definition of "security" under the Securities Act and the Exchange Act.[40] We also indicated that we were in the process of implementing the Title VII statutory provisions governing the registration and regulation of security-based SEFs.[41] We had proposed rules to implement these provisions, but the particular characteristics of trading platforms that security-based SEFs will be permitted to operate would not be known until we adopted final rules for security-based SEFs. We indicated that we were evaluating the comments we had received on these proposed rules, but that we had not yet adopted final rules implementing the Title VII statutory provisions governing the registration and regulation of security-based SEFs.[42] Moreover, we indicated that we were evaluating such comments in connection with our consideration of the comments we have received on the interim final rules given commenters' concerns regarding the operation of security-based swap trading platforms.[43]

C. Extension of the Interim Final Rules

In this release, we are extending the expiration dates in the interim final

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[25] *Id.*

[26] *See* SIFMA Letter and SIFMA/ISDA Letter.

[27] *See* SIFMA/ISDA Letter.

[28] *See* SIFMA Letter.

[29] *See* SIFMA Letter and SIFMA/ISDA Letter.

[30] The category of security-based swaps that would be covered by this request for relief is broader in some ways than the category of security-based swaps covered by the exemptions provided in the interim final rules. As noted in footnote 6 above, the exemptions provided in the interim final rules apply to security-based swaps that were defined as "security-based swap agreements" prior to the Title VII effective date. That definition of "security-based swap agreement" does not include security-based swaps that are based on or reference only loans and indexes only of loans.

[31] *See* SIFMA Letter and SIFMA/ISDA Letter. These commenters limited their request for relief to security-based swap transactions not involving an eligible clearing agency. *Id.* We adopted exemptions under the Securities Act, the Exchange Act, and the Trust Indenture Act for security-based swap transactions involving an eligible clearing agency. *See* Rule 239 under the Securities Act [17 CFR 230.239], Rules 12a–10 and 12h–1(h) under the Exchange Act [17 CFR 240.12a–10 and 240.12h–1(h)], and Rule 4d–11 under the Trust Indenture Act of 1939 [17 CFR 260.4d–11]. *See also Exemptions for Security-Based Swaps Issued By Certain Clearing Agencies*, Release No. 33–9308 (Mar. 30, 2012), 77 FR 20536 (Apr. 5, 2012) ("Cleared SBS Exemptions Adopting Release"). These exemptions do not apply to security-based swap transactions not involving an eligible clearing agency, even if the security-based swaps subsequently are cleared in transactions involving an eligible clearing agency. *Id.*

[32] *See* SIFMA/ISDA Letter.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *See* letter from Richard M. Whiting, Executive Director and General Counsel, Financial Services Roundtable, Robert Pickel, Chief Executive Officer, ISDA, and Kenneth E. Bentsen, Jr., Executive Vice President, Public Policy and Advocacy, SIFMA, dated Jan. 31, 2012 ("FSR/ISDA/SIFMA Letter"); and letter from Scott Pintoff, General Counsel, GFI Group Inc., dated Jul. 25, 2011 ("GFI Letter"). These letters were submitted in response to our request for comment in the Cleared SBS Exemptions Proposing Release. *See* footnote 19 above.

[37] *See* GFI Letter and FSR/ISDA/SIFMA Letter. The GFI Letter suggested that we provide permanent exemptions under the Securities Act, the Exchange Act, and the Trust Indenture Act for security-based swap transactions entered into between eligible contract participants and effected through any trading platform similar to the proposed exemptions for security-based swap transactions involving an eligible clearing agency. This commenter did not provide any explanation as to why such exemptions were needed, including how security-based swap trading platforms operate, that would enable us to evaluate whether relief is necessary or appropriate. *See* Cleared SBS Exemptions Adopting Release. The FSR/ISDA/SIFMA Letter requested relief under the Exchange Act and the Trust Indenture Act, but did not request relief under the Securities Act. However, two of these commenters subsequently submitted the SIFMA Letter and the SIFMA/ISDA Letter to request relief under the Securities Act. *See* footnote 31 above and accompanying text.

[38] *See* Cleared SBS Exemptions Adopting Release.

[39] *See* footnote 8 above. We had received a request from a commenter to extend the expiration dates in the interim final rules. *See* letter from Kenneth E. Bentsen, Jr., Executive Vice President, Public Policy and Advocacy, SIFMA, dated December 20, 2012.

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

rules from February 11, 2014 to February 11, 2017. We are still in the process of implementing Title VII, which imposes a comprehensive regime for the regulation of security-based swaps under the federal securities laws, including the clearing, exchange trading, and reporting of security-based swap transactions. We have adopted some rules under Title VII, including joint rules with the CFTC further defining certain Title VII definitions,[44] rules establishing the procedure by which clearing agencies submit security-based swaps for determination as to whether those instruments should be subject to mandatory clearing under Title VII,[45] and rules establishing standards for how registered clearing agencies should manage their risks and run their operations.[46] We also have issued a policy statement proposing the sequencing of compliance dates for final rules that we may adopt to complete the implementation of the security-based swaps regulatory regime ("sequencing policy statement").[47] While we are working toward fulfilling the requirements of Title VII in a thorough and deliberative manner that includes significant public input and coordination with other regulators, we have not yet adopted final rules completing the implementation of the security-based swaps regulatory regime.

Subsequent to the extension of the expiration dates in the interim final rules in February 2013, we completed proposing nearly all of the rules required to be adopted by Title VII to implement the security-based swaps regulatory regime.[48] Most recently, we proposed rules and interpretations addressing the application of the security-based swap provisions of Title VII to cross-border security-based swap transactions and to non-U.S. persons that act in capacities regulated under the Dodd-Frank Act.[49] In light of the substantially complete picture of the proposed security-based swaps regulatory regime, as well as the fact that the CFTC has adopted nearly all of its rules required by Title VII to implement the swaps regulatory regime,[50] we reopened the comment period for the proposals implementing the security-based swaps regulatory regime and the sequencing policy statement to provide the public with an additional opportunity to analyze and comment upon the proposed security-based swaps regulatory regime.[51]

As we consider final rules completing implementation of the security-based swaps regulatory regime, we are evaluating the additional comments we received after reopening the comment period. We also are considering the CFTC's experiences with implementation of the swaps regulatory regime and the extent to which our final rules should harmonize with the CFTC's final rules implementing the swaps regulatory regime. However, we do not expect to complete such evaluation and adopt final rules before February 11, 2014, the current expiration date of the interim final rules. We do not believe that we can complete our evaluation of the implications for security-based swaps and determine whether other regulatory action is appropriate until we progress further in our consideration of final rules completing the implementation of the security-based swaps regulatory regime.

For example, we are considering final rules implementing the Title VII statutory provisions governing the registration and regulation of security-based SEFs. We have proposed rules to implement these provisions, but the particular characteristics of trading platforms that security-based SEFs will be permitted to operate will not be known until we adopt final rules for security-based SEFs. As discussed above, we received comments on the interim final rules that expressed concerns regarding the implications for security-based swaps under the Securities Act as a result of the possible operation of security-based SEFs.[52] We believe that our determination about possible regulatory action for security-based swaps is directly affected by our consideration of final rules completing the implementation of the Title VII statutory provisions governing the registration and regulation of security-based SEFs.[53]

If the interim final rules expire before we complete our evaluation of the implications for security-based swaps as securities and determine whether other regulatory action is appropriate, market participants entering into security-based swap transactions will have to consider whether they need to register the offer and sale of the security-based swaps under the Securities Act. Market participants also will have to consider whether they may be required to comply with the registration provisions of the Exchange Act applicable to classes of securities and the indenture provisions of the Trust Indenture Act. We believe that requiring compliance with these provisions while we evaluate the implications for security-based swaps as securities and determine whether other regulatory action is appropriate could have an impact on the operation of the security-based swaps market. Thus, the interim final rules are needed to allow market participants that meet the conditions of the interim final rules to continue to enter into security-based swap transactions without concern that such activities may not comply with the applicable provisions of the Securities Act, the Exchange Act, and the Trust Indenture Act.

Based on the foregoing, we believe that it is necessary and appropriate in the public interest and consistent with the protection of investors to continue providing the exemptions from all provisions of the Securities Act (other than the Section 17(a) antifraud provisions), the registration requirements of the Exchange Act relating to classes of securities, and the indenture provisions of the Trust Indenture Act for those security-based

[44] *See* Intermediary Definitions Adopting Release and *Further Definition of "Swap," "Security-Based Swap," and "Security-Based Swap Agreement"; Mixed Swaps; Security-Based Swap Agreement Recordkeeping*, Release No. 33–9338 (Jul. 18, 2012), 77 FR 48208 (Aug. 13, 2012).

[45] *See Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies; Technical Amendments to Rule 19b–4 and Form 19b–4 Applicable to All Self-Regulatory Organizations*, Release No. 34–67286 (Jun. 28, 2012), 77 FR 41602 (Jul. 13, 2012).

[46] *See Clearing Agency Standards*, Release No. 34–68080 (Oct. 22, 2012), 77 FR 66219 (Nov. 2, 2012).

[47] *See Statement of General Policy on the Sequencing of the Compliance Dates for Final Rules Applicable to Security-Based Swaps Adopted Pursuant to the Securities Exchange Act of 1934 and the Dodd-Frank Wall Street Reform and Consumer Protection Act*, Release No. 34–67177 (Jun. 11, 2012), 77 FR 35625 (Jun. 14, 2012).

[48] We have not yet proposed rules regarding the reporting and recordkeeping requirements to which security-based swap dealers and major security-based swap participants will be subject pursuant to Section 15F(f) of the Exchange Act. 15 U.S.C. 78o–10(f).

[49] *See Cross-Border Application of Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act; Re-Proposal of Regulation SBSR and Certain Rules and Forms Relating to the Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants*, Release No. 34–69490 (May 1, 2013), 78 FR 30967 (May 23, 2013).

[50] CFTC Chairman Gary Gensler has noted that the CFTC has "largely completed the swaps market rulemaking, with 80 percent behind us. . . ." Gary Gensler, Chairman, CFTC, Opening Remarks at CFTC Public Roundtable on "Futurization of Swaps" (Jan. 31, 2013) (transcript available at *http://www.cftc.gov/PressRoom/SpeechesTestimony/apagensler-130*).

[51] *See Reopening of Comment Periods for Certain Rulemaking Releases and Policy Statement Applicable to Security-Based Swaps Proposed Pursuant to the Securities Exchange Act of 1934 and the Dodd-Frank Wall Street Reform and Consumer Protection Act*, Release No. 34–69491 (May 1, 2013), 78 FR 30800 (May 23, 2013).

[52] *See* footnote 16 above and accompanying text.

[53] Moreover, under the swaps regulatory regime as implemented, we are considering issues that may arise under the federal securities laws from the possible trading of security-based swaps on swap execution facilities.

swaps that prior to the Title VII effective date were security-based swap agreements, provided certain conditions are met. Accordingly, due to the interrelationship between the interim final rules and the ongoing implementation of the security-based swaps regulatory regime, and based on our consideration of comments we have received to date on these matters, we have determined that it is necessary and appropriate to extend the expiration dates in the interim final rules from February 11, 2014 to February 11, 2017.[54] If we adopt further rules relating to issues raised by the application of the Securities Act or the other federal securities laws to security-based swaps before February 11, 2017, we may determine to alter the expiration dates in the interim final rules as part of that rulemaking. We only are extending the expiration dates in the interim final rules; we are not making any other changes to the interim final rules.

II. Certain Administrative Law Matters

Section 553(b) of the Administrative Procedure Act[55] generally requires an agency to publish notice of a proposed rulemaking in the **Federal Register**. This requirement does not apply, however, if the agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." [56] Further, the Administrative Procedure Act also generally requires that an agency publish an adopted rule in the **Federal Register** 30 days before it becomes effective.[57] This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner.[58] We, for good cause, find that notice and solicitation of comment before adopting the amendments to the interim final rules is impracticable, unnecessary, or contrary to the public interest. We also find good cause not to delay the effective date of the amendments to the interim final rules.

For the reasons we discuss throughout this release, we believe that we have good cause to act immediately to adopt the amendments to the interim final rules to extend the expiration dates in the interim final rules. The extension of the expiration dates in the interim final rules is intended to minimize disruptions and costs to the security-based swaps market that could occur if the interim final rules expire. The interim final rules are needed to allow market participants that meet the conditions of the interim final rules to continue to enter into security-based swap transactions without concern that such activities will be subject to the registration requirements of the Securities Act and the Exchange Act and the indenture qualification provisions of the Trust Indenture Act while we complete our evaluation of the implications for security-based swaps and determine whether other regulatory action is appropriate.

As noted above, we currently are considering final rules completing the implementation of the security-based swaps regulatory regime. As part of such consideration, we are evaluating the additional comments we received after reopening the comment period for the proposals implementing the security-based swaps regulatory regime and the sequencing policy statement and the CFTC's experiences with implementation of the swaps regulatory regime. However, we do not expect to complete such evaluation and adopt final rules before February 11, 2014, the current expiration date of the interim final rules. We do not believe that we can complete our evaluation of the implications for security-based swaps and determine whether other regulatory action is appropriate until we progress further in our consideration of final rules completing the implementation of the security-based swaps regulatory regime. We believe that our determination regarding possible regulatory action for security-based swaps is directly affected by our consideration of final rules completing the implementation security-based swaps regulatory regime. Moreover, under the swaps regulatory regime as implemented, we are considering issues that may arise under the federal securities laws from the possible trading of security-based swaps on swap execution facilities.

Absent an extension, the interim final rules will expire on February 11, 2014. The interim final rules have been in place since July 2011 and market participants have relied on them to enter into security-based swap transactions. Extending the expiration dates in the interim final rules will not affect the substantive provisions of the interim final rules and will allow market participants that meet the conditions of the interim final rules to continue to enter into security-based swap transactions without concern that such activities will be subject to the registration requirements of the Securities Act and the Exchange Act and the indenture qualification provisions of the Trust Indenture Act while we complete our evaluation of the implications for security-based swaps as securities and determine whether other regulatory action is appropriate. Based on the foregoing and for the reasons we discuss throughout this release, we find that there is good cause to have the amendments to the interim final rules effective upon publication in the **Federal Register** and that notice and solicitation of comment in advance of the effectiveness of the amendments to the interim final rules is impracticable, unnecessary or contrary to the public interest.[59]

III. Economic Analysis

We are mindful of the costs imposed by, and the benefits to be obtained from, our rules. Section 2(b) of the Securities Act and Section 3(f) of the Exchange Act require the Commission, whenever it engages in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action would promote efficiency, competition, and capital formation.[60] In addition, Section 23(a)(2) of the Exchange Act requires the Commission, when making rules under the Exchange Act, to consider the impact such rules would have on competition.[61] Section 23(a)(2) of the Exchange Act prohibits the Commission from adopting any rule

[54] In conjunction with the extension of the expiration dates in the interim final rules, we also are extending certain of the temporary relief we adopted in July 2011 that provided exemptions from compliance with certain provisions of the Exchange Act. This relief also is set to expire on February 11, 2014 and exempts security-based swap activities from the application of the Exchange Act other than certain antifraud and anti-manipulation provisions, all Exchange Act provisions related to security-based swaps added or amended by Title VII of the Dodd-Frank Act, including the amended definition of "security" in Section 3(a)(10), and certain other Exchange Act provisions. *See Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with the Revision of the Definition of "Security" to Encompass Security-Based Swaps*, Release No. 34–71485 (Feb. 5, 2014). *See also Order Granting Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with the Pending Revisions of the Definition of "Security" to Encompass Security-Based Swaps*, Release No. 34–64795 (Jul. 1, 2011), 76 FR 39927 (Jul. 7, 2011).

[55] 5 U.S.C. 553(b).

[56] *Id.*

[57] *See* 5 U.S.C. 553(d).

[58] *Id.*

[59] This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the rule amendment to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a federal agency finds that notice and public comment are "impractical, unnecessary or contrary to the public interest," a rule "shall take effect at such time as the federal agency promulgating the rule determines").

[60] *See* 15 U.S.C. 77b(b) and 15 U.S.C. 78c(f).

[61] *See* 15 U.S.C. 78w(a)(2).

that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[62]

As discussed above, we are adopting amendments to the interim final rules to extend the expiration dates in the interim final rules to February 11, 2017. Extending the expiration dates in the interim final rules is intended to minimize disruptions and costs to the security-based swaps market that could occur on the current expiration date of the interim final rules. The interim final rules are needed to allow market participants that meet the conditions of the interim final rules to continue to enter into security-based swap transactions without concern that such activities will be subject to the registration requirements of the Securities Act and the Exchange Act and the indenture qualification provisions of the Trust Indenture Act.

The interim final rules currently in effect serve as the economic baseline against which the costs and benefits, as well as the impact on efficiency, competition, and capital formation, of the amendments are measured. Because the extension of the expiration dates in the interim final rules maintains the status quo, we do not expect additional significant costs or benefits to result from the extension. We also do not expect the extension to have additional significant effects on efficiency, competition, or capital formation. The interim final rules will continue to exempt certain security-based swaps from all provisions of the Securities Act, other than the Section 17(a) antifraud provisions,[63] as well as exempt these security-based swaps from Exchange Act registration requirements, and from the provisions of the Trust Indenture Act, provided certain conditions are met.

In the alternative, we could allow the interim final rules to expire by not extending their expiration date. In this scenario, market participants who continue to effect security-based swap transactions would have to determine whether another exemption from the registration requirements of the Securities Act is available so that they may be able to rely on that exemption. If no Securities Act exemptions are available for a security-based swap transaction following the expiration of the interim final exemptions, such a transaction would have to be registered under the Securities Act. The counterparties to such a transaction also would have to consider whether they need to comply with the registration requirements of the Exchange Act and the indenture provisions of the Trust Indenture Act. We believe that requiring compliance with these provisions at this time for security-based swap transactions between eligible contract participants likely would disrupt and impose new costs on this segment of the security-based swaps market. For example, if market participants are required to register the offer and sale of these security-based swaps under the Securities Act, they would have to incur the additional costs of such registration, including legal and accounting costs, as well as the costs associated with preparing the disclosure documents describing these security-based swaps. Market participants also may incur costs associated with the registration of these security-based swaps under the Exchange Act and compliance with the Trust Indenture Act, including preparing indentures and arranging for the services of a trustee.

It is also possible that if we were to allow the interim final rules to expire, efficiency and capital formation may be impaired. Failing to extend the expiration dates in the interim final rules may result in disruptions and costs to the security-based swaps market that could impede efficiency. Additionally, some market participants may not continue to participate in certain security-based swap transactions if compliance with these provisions were infeasible (economically or otherwise). In that case, capital formation may be impaired to the extent that some market participants use these security-based swap transactions to hedge risks, including those related to the issuance of the referenced securities (as may occur with equity swaps and the issuance of convertible bonds). For example, if registration of these transactions is required under our existing Securities Act registration scheme, issuers of security-based swaps may be forced to provide disclosure about their security-based swap positions that might not otherwise be disclosed to the market. This position disclosure could lead to a decreased use of security-based swaps by these market participants, which could potentially impair capital formation to the extent counterparties might use security-based swaps for hedging their exposure to issuers of referenced securities.

We also recognize that there would be other effects associated with letting the interim final rules expire. Without the exemptions provided for in the interim final rules, a market participant may have to file a registration statement covering the offer and sale of the security-based swaps, may have to register the class of security-based swaps that it has issued under the Exchange Act, and may have to satisfy the applicable provisions of the Trust Indenture Act, which would provide investors with additional information and in certain cases civil remedies. For example, a registration statement covering the offer and sale of the security-based swaps may provide certain information about the market participants, the security-based swap contract terms, and the identification of the particular reference securities, issuers, or loans underlying the security-based swap. Additionally, although investors currently may pursue antifraud actions in connection with the purchase and sale of security-based swaps under Section 10(b) of the Exchange Act,[64] if market participants were required to file registration statements under the Securities Act, investors may also be able to pursue civil remedies under Sections 11 or 12 of the Securities Act.[65]

IV. Paperwork Reduction Act

The interim final rules do not impose any new "collections of information" within the meaning of the Paperwork Reduction Act of 1995 ("PRA"),[66] nor do they create any new filing, reporting, recordkeeping, or disclosure reporting requirements. Accordingly, we did not submit the interim final rules to the Office of Management and Budget for review in accordance with the PRA.[67] We requested comment on whether our conclusion that there are no collections of information is correct, and we did not receive any comment.

V. Regulatory Flexibility Act Certification

We hereby certify pursuant to 5 U.S.C. 605(b) that extending the expiration dates in the interim final rules will not have a significant economic impact on a substantial number of small entities.[68] The interim final rules apply only to counterparties that may engage in security-based swap transactions in reliance on the interim final rule providing an exemption under the Securities Act. The interim final rule

[62] *Id.*

[63] *See* 15 U.S.C. 77q(a).

[64] *See* 15 U.S.C. 78j(b).

[65] *See* 15 U.S.C. 77k–l. Regardless of the extension, however, we can always pursue an antifraud action in the offer and sale of security-based swaps under Section 17(a) of the Securities Act. *See* 15 U.S.C. 77q.

[66] 44 U.S.C. 3501 *et seq.*

[67] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[68] We certified pursuant to 5 U.S.C. 605(b) that the interim final rules will not have a significant economic impact on a substantial number of small entities. *See* Interim Final Rules Adopting Release. We received no comments on that certification.

under the Securities Act provides that the exemption is available only to security-based swaps that are entered into between eligible contract participants, as that term is defined in Section 1a(12) of the Commodity Exchange Act as in effect prior to the Title VII effective date, and other than with respect to persons determined by the CFTC to be eligible contract participants pursuant to Section 1a(12)(C) of the Commodity Exchange Act. Based on our existing information about the security-based swaps market, including our existing information about participants in the security-based swaps market, we believe that the interim final rules apply to few, if any, small entities.[69] For this reason, the extension of the expiration dates in the interim final rules should not have a significant economic impact on a substantial number of small entities.

VI. Statutory Authority and Text of the Rules and Amendments

The amendments described in this release are being adopted under the authority set forth in Sections 19 and 28 of the Securities Act, Sections 12(h), 23(a) and 36 of the Exchange Act, and Section 304(d) of the Trust Indenture Act.

List of Subjects in 17 CFR Parts 230, 240 and 260

Reporting and recordkeeping requirements, Securities.

Text of the Rules and Amendments

For the reasons set out in the preamble, the Commission amends 17 CFR parts 230, 240, and 260 as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l*, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

§ 230.240 [Amended]

■ 2. In § 230.240(c), in the first sentence, remove the words "February 11, 2014" and add, in their place, the words "February 11, 2017".

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 3. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78n–1, 78o, 78o–4, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.*; 18 U.S.C. 1350; and 12 U.S.C. 5221(e)(3), unless otherwise noted.

* * * * *

§ 240.12a–11 [Amended]

■ 4. In § 240.12a–11(b), in the first sentence, remove the words "February 11, 2014" and add, in their place, the words "February 11, 2017".

§ 240.12h–1 [Amended]

■ 5. In § 240.12h–1(i), in the second sentence, remove the words "February 11, 2014" and add, in their place, the words "February 11, 2017".

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

■ 6. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 77sss, 78*ll*(d), 80b–3, 80b–4, and 80b–11.

§ 260.4d–12 [Amended]

■ 7. In § 260.4d–12, in the second sentence, remove the words "February 11, 2014" and add, in their place, the words "February 11, 2017".

Dated: February 5, 2014.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2014–02833 Filed 2–7–14; 8:45 am]

BILLING CODE 8011–01–P

[69] For example, as revealed in a current survey conducted by Office of the Comptroller of the Currency, 100.0% of credit default swap positions held by U.S. commercial banks and trust companies are held by those with assets over $10 billion. *See* Office of the Comptroller of the Currency, "Quarterly Report on Bank Trading and Derivatives Activities Third Quarter 2013" (2013).

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 403 and 429

[Docket No. SSA–2013–0064]

RIN 0960–AH65

Change of Address for Requests: Testimony by Employees and the Production of Records and Information in Legal Proceedings, Claims Against the Government Under the Federal Tort Claims Act of 1948, and Claims Under the Military Personnel and Civilian Employees' Claim Act of 1964

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: This final rule updates the address used to file applications for testimony of a Social Security Administration employee and claims made pursuant to either the Federal Tort Claims Act of 1948 or the Military Personnel and Civilian Employees' Claims Act of 1964.

DATES: This final rule will be effective February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Daniel F. Callahan, Office of the General Counsel, Social Security Administration, 6401 Security Boulevard, Room 617 Altmeyer Building, Baltimore, MD 21235–6401, (410) 965–4296. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION: We are updating our regulations at 20 CFR 403.120, 429.102, and 429.202 to reflect a change in the address where an individual may contact us to request that an employee of the Social Security Administration testify in a legal proceeding to which we are not a party, or to file a claim against the Government under either the Federal Tort Claims Act of 1948 or the Military Personnel and Civilian Employees' Claims Act of 1964. The new address is: Social Security Administration, Office of the General Counsel, Office of General Law, 6401 Security Boulevard, Room 617 Altmeyer Building, Baltimore, Maryland 21235–6401.

We are not making any substantive changes to the regulations.

Regulatory Procedures

Justification for Final Rule

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553

when developing our regulations.[1] The APA provides exceptions to its prior notice and public comment procedures when an agency finds good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In the case of this final rule, we have determined that good cause exists for dispensing with the notice and public comment procedures because such procedures are unnecessary.[2]

Executive Order 12866

We consulted with the Office of Management and Budget and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it only affects individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income; 96.007, Social Security—Research and Demonstration; 96.008, Social Security—Work Incentives Planning and Assistance Program; 96.009 Social Security State Grants for Work Incentives Assistance to Disabled Beneficiaries; 96.020, Special Benefits for Certain World War II Veterans; and 96.021 Social Security Economic Recovery Act Payments)

List of Subjects

20 CFR Part 403

Courts, Government employees, Reporting and recordkeeping requirements.

20 CFR Part 429

Administrative practice and procedure, Claims, Government employees, Penalties.

[1] 42 U.S.C. 902(a)(5).

[2] 5 U.S.C. 553(b)(B).

Dated: February 4, 2014.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we amend 20 CFR chapter III, parts 403 and 429 as follows:

PART 403—TESTIMONY BY EMPLOYEES AND THE PRODUCTION OF RECORDS AND INFORMATION IN LEGAL PROCEEDINGS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 702(a)(5) and 1106 of the Act, (42 U.S.C. 902(a)(5) and 1306); 5 U.S.C. 301; 31 U.S.C. 9701.

■ 2. Amend § 403.120 to revise paragraph (c) to read as follows:

§ 403.120 How do you request testimony?

* * * * *

(c) You must send your application for testimony to: Social Security Administration, Office of the General Counsel, Office of General Law, 6401 Security Boulevard, Room 617 Altmeyer Building, Baltimore, Maryland, 21235–6401, Attn: *Touhy* Officer. (If you are requesting testimony of an employee of the Office of the Inspector General, send your application to the address in § 403.125.)

* * * * *

PART 429—ADMINISTRATIVE CLAIMS UNDER THE FEDERAL TORT CLAIMS ACT AND RELATED STATUTES

■ 3. The authority citation for part 429 continues to read as follows:

Authority: Secs. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)); 28 U.S.C. 2672; 28 CFR 14.11; 31 U.S.C. 3721.

Subpart A—Claims Against the Government Under the Federal Tort Claims Act

■ 4. Amend § 429.102 to revise paragraph (c) to read as follows:

§ 429.102 How do I file a claim under this subpart?

* * * * *

(c) *Where to obtain claims forms and file claims.* You can obtain claims forms by writing to the Social Security Administration, Office of the General Counsel, Office of General Law, 6401 Security Boulevard, Room 617 Altmeyer Building, Baltimore, Maryland 21235–6401. You may also file your claim with the Social Security Administration at this same address.

Subpart B—Claims Under the Military Personnel and Civilian Employees' Claims Act of 1964

■ 5. Amend § 429.202 to revise paragraph (b) to read as follows:

§ 429.202 How do I file a claim under this subpart?

* * * * *

(b) *Where to file.* You must file your claim with the Social Security Administration, Office of the General Counsel, Office of General Law, 6401 Security Boulevard, Room 617 Altmeyer Building, Baltimore, Maryland 21235–6401.

* * * * *

[FR Doc. 2014–02853 Filed 2–7–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–385]

Schedules of Controlled Substances: Temporary Placement of Four Synthetic Cannabinoids Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule four synthetic cannabinoids into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The substances are: Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids and their optical, positional, and geometric isomers, salts and salts of isomers into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export,

engage in research, conduct instructional activities, and possess), or propose to handle these synthetic cannabinoids.

DATES: This final order is effective February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, Appendix to Subpart R of Part 0, Sec. 12.

Background

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.[1] The Deputy Administrator transmitted notice of his intent to place PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I on a temporary basis to the Assistant Secretary by letter dated November 7, 2013. The Assistant Secretary responded to this notice by letter dated January 27, 2014, and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I of the CSA.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). As PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA under section 505 of the FDCA, 21 U.S.C. 355, the conditions of 21 U.S.C. 811(h)(1) have been satisfied. As required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule these four synthetic cannabinoids was published in the **Federal Register** on January 10, 2014. 79 FR 1776.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Synthetic Cannabinoids

Synthetic cannabinoids are a large family of compounds that are functionally (biologically) similar to delta9-tetrahydrocannabinol (THC), the main active ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory. Two of the synthetic cannabinoids currently controlled (CP–47,497 and cannabicyclohexanol) were first synthesized in the early 1980s for research purposes in the investigation of the cannabinoid system. JWH–018, JWH–073, and JWH–200 (temporarily scheduled on March 1, 2011, at 76 FR 11075 and permanently scheduled on July 9, 2012, by Section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112–144) were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids.

According to forensic laboratory reports, the initial appearance of synthetic cannabinoids in herbal

[1] Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within the HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection (CBP) first encountered products using brand names such as "Spice." Prior to appearing on the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents, some European countries banned these products/chemicals. According to CBP, a number of the synthetic cannabinoids appeared to originate from foreign sources.

Detailed chemical analyses by DEA and other agencies have found synthetic cannabinoids applied on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material.

The vast majority of cannabinoids are manufactured in Asia by individuals who are not bound by any manufacturing requirements or quality control standards. The bulk products are smuggled into the United States typically as misbranded imports. These chemicals are generally found in powder form or are dissolved in solvents, such as acetone, before being applied to the plant material comprising the "herbal incense" products. After local distributors apply the drug to the leafy material, they package it for retail distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of drug in each package. According to Internet discussion boards and law enforcement encounters, spraying or mixing the synthetic cannabinoids on plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). They are sold under hundreds of different brand names, including "Spice," "K2," "Blaze," "Red X Dawn," "Paradise," "Demon," "Black Magic," "Spike," "Mr. Nice Guy," "Ninja," "Zohai," "Dream," "Genie," "Sence," "Smoke," "Skunk," "Serenity," "Yucatan," "Fire," and "Crazy Clown."

Law enforcement personnel have encountered dosage form and packaging operations in residential neighborhoods, garages, and warehouses. Throughout this process, there is no concern for preventing contamination of the product, consistent dosage, or the adverse health consequences that may occur from ingesting the drug. As proposed in the scientific literature, the risk of adverse health effects is further increased by the fact that similarly labeled products vary in the composition and concentration of synthetic cannabinoids applied on the plant material.

There is an incorrect assumption that these products are safe. Numerous states, local jurisdictions, and the international community have controlled many synthetic cannabinoids. These substances have no accepted medical use in the United States and have been reported to produce adverse health effects in those who abuse them.

PB–22, 5F–PB–22, AB–FUBINACA and ADB–PINACA are synthetic cannabinoids that have pharmacological effects similar to the schedule I hallucinogen delta-9-tetrahydrocannabinol (THC). PB–22 and 5F–PB–22 were not reported in the scientific literature prior to their appearance on the illicit drug market. First appearing in a 2009 patent filed by the pharmaceutical manufacturer Pfizer, AB–FUBINACA was most recently reported in the scientific literature as a component of so-called "herbal products" purchased via the Internet in July 2012. ADB–PINACA was first encountered by law enforcement following reports of serious adverse events in Georgia and Colorado in August and September 2013, respectively.

From January through December 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE)[2] there were 211 reports involving PB–22, 168 reports involving 5F–PB–22, and 74 reports involving AB–FUBINACA (Queried on January 22, 2014). From January through December 2013, the National Forensic Laboratory Information System (NFLIS)[3] registered 1,318 reports containing PB–22 in 29 states, 1,294 reports containing 5F–PB–22 in 29 states, 822 reports containing AB–FUBINACA in 21 states and 40 reports containing ADB–PINACA in three states (Queried on January 22, 2014). No reports in NFLIS or STRIDE were identified for PB–22 or 5F–PB–22 prior to January 2013. No reports in NFLIS or STRIDE were identified for AB–FUBINACA prior to June 2013 or for ADB–PINACA prior to August 2013.

[2] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

[3] NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed over the last 30 years as tools for investigating the cannabinoid system. Synthetic cannabinoids intended for illicit use were first reported in the United States in a November 2008 encounter, where a shipment of "Spice" was seized and analyzed by CBP in Dayton, Ohio. Additionally around the same time, in December 2008, JWH–018 and cannabicyclohexanol (CP–47,497 C8 homologue) were identified by German forensic laboratories. Since the initial identification of JWH–018, many additional synthetic cannabinoids have been found applied on plant material and encountered as designer drug products. The majority of the substances encountered on the illicit market have not been tested beyond preliminary pre-clinical laboratory screens before clandestine operators apply them on plant material.

JWH–018 was the first synthetic cannabinoid to be identified as a product adulterant in Germany in 2008. This substance was initially synthesized as a research tool to investigate the cannabinoid system. Since then, numerous other synthetic cannabinoids have been identified as product adulterants and law enforcement has seized bulk amounts of these substances. The first synthetic cannabinoids identified as being abused included JWH–018, JWH–200, JWH–073, CP–47,497 and CP–47,497 C8 homologue, followed shortly thereafter by new generations of synthetic cannabinoids that included AM2201 and others, and eventually UR–144, XLR11 and AKB48. JWH–018, JWH–073, JWH–200, CP–47,497, and CP–47,497 C8 were temporarily scheduled on March 1, 2011 (76 FR 11075), and later permanently placed in schedule I by Section 1152 of FDASIA on July 9, 2012. Section 1152 of FDASIA amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 synthetic phenethylamines of the 2C-series) in schedule I. UR–144, XLR11 and AKB48 were temporarily scheduled on May 16, 2013 (78 FR 28735). The most recent synthetic cannabinoids emerging as drugs of abuse include PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA. These four synthetic cannabinoids, along with UR–144, XLR11 and AKB48, were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

Synthetic cannabinoid products are marketed directly to adolescents and youth who appear to be the primary abusers of synthetic cannabinoids and synthetic cannabinoid-containing products. This is supported by law enforcement encounters and reports from emergency rooms; however, all age groups have been reported by media as abusing these substances and related products.

According to recent testimony given by the Deputy Director of the Office of National Drug Control Policy (ONDCP) to the United States Senate Caucus on International Narcotics Control (September 25, 2013), current drug testing misses significant populations of synthetic cannabinoid users. This testimony describes a study showing that in a sample of men 30 years old or younger within the District of Columbia parole and probation system, 39 percent of those who cleanly passed a traditional drug screen tested positive for synthetic cannabinoids. The study continued that between one-quarter and one-third of young men who were tested in the Washington, DC criminal justice system had positive test results for synthetic cannabinoids, regardless of whether they had failed or passed a traditional drug screen.

Factor 5. Scope, Duration and Significance of Abuse

Recently, increased exposure incidents have been documented by poison control centers in the United States as the abuse of synthetic cannabinoids has been associated with both acute and long-term public health and safety concerns. From January through December 2013, according to STRIDE there were 211 reports involving PB–22; 168 reports involving 5F–PB–22; and 74 reports involving AB–FUBINACA (Queried on January 22, 2014). From January through December 2013, NFLIS registered 1,318 reports containing PB–22 in 29 states (Arkansas, Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Wisconsin and Wyoming); 1,294 reports containing 5F–PB–22 in 29 states (Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming); 822 reports containing AB–FUBINACA in 21 states (Arizona, Colorado, Connecticut, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Hampshire, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas and Wisconsin); and 40 reports containing ADB–PINACA in three states (Colorado, Georgia and Wisconsin) (Queried on January 22, 2014). No reports in NFLIS or STRIDE were identified for PB–22 or 5F–PB–22 prior to January 2013. No reports in NFLIS or STRIDE were identified for AB–FUBINACA prior to June 2013 or for ADB–PINACA prior to August 2013.

ADB–PINACA was first encountered in the United States following reports of serious adverse events in Georgia on August 23, 2013. Reports of ADB–PINACA were not found in the scientific literature prior to its emergence on the designer drug market. The Georgia Bureau of Investigation (GBI) reported on September 12, 2013, that ADB–PINACA was detected in "herbal incense" products sold under the brand name "Crazy Clown." It was later confirmed by the Centers for Disease Control and Prevention (CDC) as the substance responsible for severe adverse events in at least 22 persons who consumed the product. In addition, on August 30, 2013, the Colorado Department of Public Health and Environment (CDPHE) was notified by several hospitals of an increase in the number of patients visiting their emergency departments (EDs) with altered mental status after using "synthetic marijuana." CDC 2013. On September 8, 2013, CDPHE, with the assistance of CDC, began an epidemiologic investigation whereby 221 cases of severe illness due to ingestion of a synthetic cannabinoid were identified. Those that presented at emergency rooms in the Denver, Colorado area around September 1, 2013, had symptoms similar to those found in the August 2013 Georgia incident. Laboratory analysis of samples from the Colorado incident confirmed that the substance abused in the "herbal incense" products was ADB–PINACA.

The American Association of Poison Control Centers (AAPCC) reported receiving over 2,639 calls from January to December 2013, regarding exposures to products purportedly containing synthetic cannabinoids, although the data provided does not generally include biological sample testing that would confirm to which cannabinoids the user was exposed. A majority of these exposure incidents resulted in individuals seeking medical attention at health care facilities.

Factor 6. What, If any, Risk There Is to the Public Health

The earliest reported encounter of PB–22 was by Finnish Customs (Tulli) in Helsinki who intercepted a consignment of 54 kilograms en route from China to Russia on October 27, 2012. From January through November 2013, CBP shared information related to synthetic cannabinoid shipments encountered at United States Ports of Entry and intended for destinations within the United States: PB–22—25 encounters involving 69.6 kg; 5F–PB–22—23 encounters involving 32.9 kg; and AB–FUBINACA—9 encounters involving 16.1 kg. The DEA has reported multiple encounters of large quantities of PB–22, 5F–PB–22 and/or AB–FUBINACA that have been confirmed by forensic laboratories (STRIDE).

In late August 2013, local law enforcement in Brunswick, Georgia reported that 22 persons ranging in age from 16 to 57 presented to emergency departments with severe adverse reactions after consuming a synthetic product called "Crazy Clown." Adverse effects included the inability to stand, foaming at the mouth, violence towards police and paramedics and memory lapse. The substance responsible for these effects was later identified by the GBI as ADB–PINACA. In early September 2013, 221 patients presented to emergency departments in Colorado after having adverse reactions to a synthetic product labeled as "Black Mamba." Adverse effects included having no gag reflex, inability to breathe on their own, hallucinations and psychotic episodes as described by nurses and attending physicians. The substance in the product consumed was identified as ADB–PINACA. In addition to the incidents in Georgia and Colorado, ADB–PINACA was also identified in exhibits of plant material labeled "10X" and "20X" submitted to a laboratory in Illinois on October 7, 2013.

Health warnings have been issued by numerous state public health departments and poison control centers describing adverse health effects associated with smoking (inhaling) synthetic cannabinoid products including agitation, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations, and non-responsiveness.

Medical examiner and postmortem toxicology reports demonstrate the involvement of 5F–PB–22 in the death of at least five individuals. These reports demonstrated that 5F–PB–22 was qualitatively identified in the blood and/or urine of all five of the deceased

individuals. In addition, 5F–PB–22 intoxication was the sole cause of death in one case, while a second case stated that the cause of death was a fatal cardiac arrhythmia and/or fatal seizure in association with the use of 5F–PB–22.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses of these substances in the United States.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of PB–22, 5F–PB–22, AB–FUBINACA and ADB–PINACA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Deputy Administrator, through a letter dated November 7, 2013, notified the Assistant Secretary of the intention to temporarily place these four synthetic cannabinoids in schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily place four synthetic cannabinoids, PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA into schedule I of the CSA, and finds that placement of these synthetic cannabinoids into schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into schedule I to avoid an imminent hazard to the public safety, the final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, importing, exporting, research, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or desires to handle, PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA, must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312 as of February 10, 2014. Any person who currently handles PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA, and is not registered with the DEA, must submit an application for registration and may not continue to handle PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA as of February 10, 2014 unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA.

2. *Security.* PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of February 10, 2014.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of February 10, 2014. Current DEA registrants shall have 30 calendar days from February 10, 2014 to comply with all labeling and packaging requirements.

4. *Inventory.* Every DEA registrant who possesses any quantity of PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA on the effective date of this order, must take an inventory of all stocks of these substances on hand as of February 10, 2014, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including PB–22, 5F–PB–22, AB–FUBINACA, and ADB–PINACA) on hand on a biennial basis, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of February 10, 2014. Current DEA registrants authorized to handle PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports.* All DEA registrants who manufacture or distribute PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33 as of February 10, 2014.

7. *Order Forms.* All registrants who distribute PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of February 10, 2014.

8. *Importation and Exportation.* All importation and exportation of PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of February 10, 2014.

9. *Quota.* Only registered manufacturers may manufacture PB–22, 5F–PB–22, AB–FUBINACA, or ADB–PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

10. *Criminal Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of the CSA, occurring as of February 10, 2014 is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of a proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety. Further, the DEA believes that this temporary scheduling action final order is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to section 808(2) of the Congressional Review Act (CRA), "any rule for which an agency for good cause finds. . .that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances into schedule I because they pose a threat to public health, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding paragraphs (h)(15) through (h)(18) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(15) Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers—7222 (Other names: PB-22; QUPIC)

(16) Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers—7225 (Other names: 5-fluoro-PB-22; 5F-PB-22)

(17) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7012 (Other names: AB-FUBINACA)

(18) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7035 (Other names: ADB-PINACA)

Dated: February 5, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014–02848 Filed 2–7–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 8627]

RIN 1400–AD29

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended; TN Visas From NAFTA Countries

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: The Department of State amends its regulation pertaining to The North American Free Trade Agreement (NAFTA), by removing the petition requirement for citizens of Mexico applying for nonimmigrant visa classification as NAFTA professionals. The rule reflects changes to documentary requirements authorized under the Immigration and Nationality Act, in implementation of NAFTA.

DATES: This rule is effective February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Paul-Anthony L. Magadia, U.S. Department of State, Office of Legislation and Regulations, CA/VO/L/R, 600 19th Street NW., SA–17, Room 12–526B, Washington, DC 20522, 202–485–7641 or *magadiapl@state.gov*

SUPPLEMENTARY INFORMATION: The United States, Canada, and Mexico entered into The North American Free Trade Agreement, (NAFTA) (Section D of Annex 1603) in 1994, following enactment of the NAFTA Implementation Act (19 U.S.C. 21). NAFTA includes provisions for the entry of certain citizens of each respective signatory country into the country of either of the two others as "professionals." To gain entry as "professionals," such citizens must meet the qualification criteria for a profession listed in Appendix 1603.D.1, and be seeking temporary entry to engage in a business activity pursuant to that profession.

Section 214(e)(2) of the Immigration and Nationality Act (INA) provides for a citizen of Canada or Mexico, and the spouse and children, if accompanying or following to join, to be treated as if seeking classification, or classifiable, as a nonimmigrant under INA section 101(a)(15). Section 214(e)(3) of the INA incorporates commitments made in NAFTA Appendix 1603.D.4, directing the Attorney General to establish an annual numerical limit for citizens of Mexico seeking temporary entry to engage in such business activity in the United States. INA section 214(e)(4) establishes conditions to be satisfied before the Secretary of Homeland Security, as successor to the Attorney General, may eliminate the numerical limit. At midnight, on December 31, 2003, the Secretary exercised this authority, and, as of January 1, 2004, eliminated the limitation of 5,500 and the requirement for a petition, which was needed solely for purposes of enforcing the limitation. This change to 22 CFR part 41 will provide consistency in the regulations of both departments governing temporary entry of NAFTA professionals.

A citizen of Mexico wishing to come to the United States in TN classification no longer needs an approved petition to meet the qualification requirements, but may apply directly to the embassy or consulate abroad for a visa. The consular officer will adjudicate eligibility for TN classification and, upon approval and issuance of a visa, the applicant may apply to the Department of Homeland Security for admission to the United States under TN status.

Regulatory Findings

Administrative Procedure Act

The Department of State is of the opinion that a rulemaking that implements treaty provisions (in this case, NAFTA) is a foreign affairs function of the United States Government and is exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since this rule is exempt from 5 U.S.C. 553, the provisions of section 553(d) do not apply to this rulemaking.

In addition, this rulemaking conforms the Department of State rule to the corresponding rule administered by the Department of Homeland Security, 8 CFR 214.6(e). This eliminates ambiguity; therefore, a notice and comment period for this rule would be impractical and unnecessary. This rule is effective upon publication.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this final regulation justify its costs. The Department of State does not consider this rule to be an economically significant action within the scope of section 3(f)(1) of the Executive Order, since it is not likely to have an annual effect on the economy of $100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the rule in light of sections 3(a) and 3(b)(2) of Executive Order No. 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Immigration, Nonimmigrant Visas.

For the reasons stated in the preamble, 22 CFR part 41 is amended as follows:

PART 41—[AMENDED]

■ 1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681–795 through 2681–801; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458, as amended by section 546 of Pub. L. 109–295).

■ 2. Section 41.59 is amended by revising paragraphs (a)(2), (a)(3), and (b) and removing paragraph (a)(4).

The revisions read as follows:

§ 41.59 Professionals under the North American Free Trade Agreement.

(a) * * *

(2) The alien shall have presented to the consular officer sufficient evidence of an offer of employment in the United

States requiring employment of a person in a professional capacity consistent with NAFTA Chapter 16 Annex 1603 Appendix 1603.D.1 and sufficient evidence that the alien possesses the credentials of that profession as listed in said appendix; or

(3) The alien is the spouse or child of an alien so classified in accordance with paragraph (a)(2) of this section and is accompanying or following to join the principal alien.

(b) *Visa validity.* The period of validity of a visa issued pursuant to paragraph (a) of this section may not exceed the period established on a reciprocal basis.

* * * * *

Dated: January 22, 2014.

Janice L. Jacobs,

Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 2014–02674 Filed 2–7–14; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2014–0037]

Drawbridge Operation Regulation; Bishop Cut, Near Stockton, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the San Joaquin County highway bridge, across Bishop Cut, mile 1.0 near Stockton, CA. The deviation is necessary to allow PG&E Company to temporarily interrupt electric service to the area while installing new overhead equipment. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 8 a.m. to 4 p.m. on February 12, 2014.

ADDRESSES: The docket for this deviation, [USCG–2014–0037], is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The County of San Joaquin Public Works Department has requested a temporary change to the operation of the San Joaquin County highway bridge, mile 1.0, over Bishop Cut, near Stockton, CA. The drawbridge navigation span provides approximately 6 feet vertical clearance above Mean High Water in the closed-to-navigation position. In accordance with 33 CFR 117.143, the draw opens on signal if at least 12 hours notice is given to the San Joaquin County Department of Public Works at Stockton. Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 8 a.m. to 4 p.m. on February 12, 2014 to allow PG&E Company to install new overhead equipment in the vicinity. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies, and Disappointment Slough can be used as an alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 29, 2014.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2014–02815 Filed 2–7–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number-USCG–2013–0994]

RIN 1625–AA87

Security Zone; Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Captain of the Port of New Orleans (COTP New Orleans), under the authority of the Magnuson Act, established a Moving Security Zone on the Mississippi river from mile marker 90.0 to mile marker 106.0 above head of passes (AHP), extending 100 yards in all directions from vessels being escorted by one or more Coast Guard asset or other federal, state, or local law enforcement agency assets. The COTP New Orleans will inform the public of the existence or status of the security zones around escorted vessels in the regulated area by Marine Safety Information Bulletins or Broadcast Notice to Mariners. This moving security zone is necessary to protect vessels deemed to be in need of escort protection by the COTP New Orleans for security reasons.

DATES: This rule is effective in the **Federal Register** on February 10, 2014 and effective with actual notice for purposes of enforcement on December 31, 2013 through April 14, 2014.

ADDRESSES: Documents indicated in this preamble are parts of docket [USCG–2013–0994] and are available online at *www.regulations.gov.* They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Lieutenant Commander (LCDR) Kelly Denning, Sector New Orleans, at (504) 365–2392 or *Kelly.K.Denning@uscg.mil.* If you have questions on viewing the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

AHP Above Head of Passes
COTP Captain of the Port

DHS Department of Homeland Security
FR Federal Register
MM Mile Marker
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. Certain vessels qualifying as vessels requiring security escorts will transit through the COTP New Orleans area of responsibility. Minimal notice regarding vessel escort operations is customary for security purposes. Based on risk evaluations completed, and information gathered after evaluating the security needs for escorted vessels during a period of high activity on and around the waterway, the Coast Guard determined that a security zone is required, beginning December 31, 2013. This security zone is needed to protect persons and property, surrounding and including escorted vessels and their personnel from destruction, loss, or injury from sabotage or other subversive acts, accidents, or other causes of a similar nature during vessel escort operations. The NPRM process would be contrary to public interest by delaying the effective date or foregoing the necessary protections required for persons and property, surrounding and including escorted vessels and their personnel. Immediate action is necessary to provide both waterway and waterside security and protection for persons and property, surrounding and including escorted vessels and their personnel in this portion of the Lower Mississippi River during the listed time period.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Providing a full 30 day notice would be contrary to the public interest because immediate action is needed to provide both waterway and waterside security and protection during vessel escort operations.

B. Basis and Purpose

The purpose of this rule is to provide enhanced protections related to escorted vessels transiting a portion of the Lower Mississippi River during times of increased activity on and around the waterway. During these times, certain vessels, including high capacity passenger vessels, vessels carrying certain dangerous cargoes as defined in 33 CFR part 60, tank vessels constructed to carry oil or hazardous materials in bulk, and vessels carrying liquefied hazardous gas as defined in 33 CFR part 127 have been deemed by the COTP New Orleans to require escort protection while transiting the Lower Mississippi River between MM 90.0 to MM 106.0 AHP.

As an additional protective measure for all those transiting the waterway during the vessels escorts, the Coast Guard is establishing a temporary security zone restricting navigation in portions of the Lower Mississippi River in New Orleans, LA to provide both waterway and waterside security and protection from MM 90.0 to MM 106.0 AHP. This security zone is necessary to protect persons and property, surrounding and including escorted vessels and their personnel from destruction, loss or injury from sabotage or other subversive acts, accidents or other causes of a similar nature.

The legal basis and authorities for this rule are found in 33 U.S.C. 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish and define regulatory security zones.

C. Discussion of the Final Rule

The Coast Guard has established a moving security zone extending 100 yards in all directions from each escorted vessel as it transits the Lower Mississippi River between MM 90.0 and MM 106.0 AHP. Vessel escorts will be performed by Coast Guard assets or other Federal, State or local law enforcement agency assets and will be clearly identified by lights, vessel markings, or with agency insignia. Persons and vessels will not be allowed to remain in or transit through this security zone without the permission of the COTP New Orleans or the on-scene Coast Guard or enforcement agency asset. A vessel may request permission of the COTP New Orleans or the on-scene Coast Guard or enforcement agency asset to deviate from the requirements of this rule. Deviations from this rule may be requested from the COTP New Orleans through the on-scene Coast Guard or enforcement agency asset, via VHF Ch. 67. If permitted to enter the security zone, a vessel must proceed at the minimum safe speed and must comply with the order of the COTP New Orleans or the on-scene asset. Vessels permitted to transit through the security zone shall maintain a distance of at least 50 yards from the escorted vessel.

The COTP New Orleans will inform the public through broadcast notices to mariners of each security zone, the enforcement period for the security zone as well as any changes in the planned schedule.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). Due to its duration and location the impacts on routine navigation are expected to be minimal.

This rule is not a significant regulatory action because the rule will be in effect for short periods of time and notifications to the marine community will be made through broadcast notices to mariners. Deviation from this rule may be requested and will be considered on a case-by-case basis by the COTP New Orleans or the on-scene Coast Guard or enforcement agency asset. Approved deviations will allow other vessels transiting the area to transit through the outer 250 yards of the security zone. Additionally, the security zone is located within the New Orleans Harbor Vessel Service Area where vessels are required to check in when entering the area or departing berth. This check in requirement can assist in early review and granting of permission to deviate from the rule. Therefore, the impacts on routine navigation are expected to be minimal.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels, intending to transit within 100 yards of an escorted vessel between MM 90.0 and MM 106.0 of the Lower Mississippi River. This security zone will not have significant impact on a substantial number of small entities because of its location and short durations and notifications to the marine community will be made through broadcast notices to mariners. Deviation from this rule may be requested and will be considered on a case-by-case basis by the COTP New Orleans or the on-scene Coast Guard or enforcement agency asset. Approved deviations will allow other vessels transiting the area to transit through the outer 250 yards of the security zone. Additionally, the security zone is located within the New Orleans Harbor Vessel Service Area where vessels are required to check in when entering the area or departing berth. This check in requirement can assist in early review and granting of permission to deviate from the rule.

If you are a small business entity and are significantly affected by this regulation please contact Lieutenant Commander (LCDR) Kelly Denning, Sector New Orleans, at (504) 365–2392 or *Kelly.K.Denning@uscg.mil.*

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a "significant energy action" under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Commandant Instruction. An environmental analysis checklist and a categorical exclusion determination will be made available as indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 2. Add § 165.T08–0994 to read as follows:

§ 165.T08–0994 Security Zone; Mississippi River, New Orleans, LA.

(a) *Location.* Lower Mississippi River, from mile marker 90.0 to mile marker 106.0 above head of passes, extending 100 yards in all directions of escorted vessels.

(b) *Effective date.* This rule is effective in the **Federal Register** on February 10, 2014 and effective with actual notice for purposes of enforcement on December 31, 2013 through April 14, 2014.

(c) *Periods of Enforcement.* This rule will be enforced during vessel escorts performed by Coast Guard assets or other Federal, State or local law enforcement agency assets clearly identified by lights, vessel markings, or agency insignia. The Captain of the Port (COTP) New Orleans or a COTP New Orleans designated representative will inform the public through broadcast notices to mariners of security zone enforcement periods as well as any changes that may occur.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, remaining in, entry into, or transiting within this security zone is prohibited. Section § 165.33 also contains other general requirements.

(2) Vessels requiring deviation from this rule must request permission from the COTP New Orleans through the on-scene Coast Guard or other agency asset, via VHF Ch. 67.

(i) Requests for deviation may include requests to enter, remain in, or transit through certain parts of the security zone. If a deviation from the rule results in permission to enter, remain in, or transit through the security zone, all vessels shall operate at the minimum speed necessary to maintain a safe course, unless required to maintain speed by the Navigation Rules, and shall proceed as directed by the Coast Guard.

(ii) If authorized to operate within the security zone, no vessel or person is allowed within 50 yards of the escorted vessel. A specific request for deviation from this rule to operate within 50 yards of the escorted vessels must be requested and will be considered on a case-by-case basis by the COTP New Orleans.

(3) All persons and vessels shall comply with the instructions of the COTP New Orleans and designated personnel. Designated personnel include commissioned, warrant and petty officers of the U.S. Coast Guard, and local, state, and federal law enforcement officers on clearly identified law enforcement agency vessels.

(4) Informational Broadcasts. The Captain of the Port or a designated representative will inform the public through marine safety information bulletins or broadcast notices to mariners of the enforcement of the security zone.

Dated: December 30, 2013.

P.C. Schifflin,

Captain, U.S. Coast Guard, Acting Captain of the Port New Orleans.

[FR Doc. 2014–02196 Filed 2–7–14; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 27

[WT Docket No. 12–357; FCC 13–88]

Service Rules for the Advanced Wireless Services H Block-Implementing Section 6401 of the Middle Class Tax Relief and Job Creation Act of 2012 Related to the 1915–1920 MHz and 1995–2000 MHz Bands

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years revisions to FCC Form 603, OMB Control Number 3060–0800, and FCC Form 608, OMB Control Number 3060–1058, associated with the Commission's Report and Order (*R&O*), Service Rules for the Advanced Wireless Services H Block-Implementing Section 6401 of the Middle Class Tax Relief and Job Creation Act of 2012 Related to the 1915–1920 MHz and 1995–2000 MHz Bands. A notice announcing the effective date of the service rules and revisions to the FCC Form 601 was published on January 17, 2014 in the **Federal Register**.

DATES: The rules §§ 1.946, 27.10, 27.12, and 27.17 effective on January 17, 2014, pursuant to a rule published at 79 FR 3133 (January 17, 2014). The corresponding revisions to the existing collections on FCC Form 603, OMB Control Number 3060–0800, and FCC Form 608, OMB Control Number 3060–1058, are effective February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Dorothy Stifflemire, Wireless Telecommunications Technologies, Systems Innovation Division, at (202) 418–7349 or by email at *Dorothy.Stifflemire@fcc.gov <mailto:Dorothy.Stifflemire@fcc.gov>*.

SUPPLEMENTARY INFORMATION: This document announces that, on January 27, 2014, OMB approved, for a period of three years, the revised information collection requirements for the FCC Forms 603 and 608 that were submitted to OMB for review and described in a 30-day notice published at 78 FR 77676, December 24, 2013. These OMB approved revisions add the national security certification required by § 6004 of the Middle Class Tax Relief and Job Creation Act of 2012, 47 U.S.C 1404, to the FCC Forms 603 and 608. The Commission has already obtained OMB approval for revisions to its previously-approved information collections for FCC Forms 175 and 601. The effective date for the revisions to the existing collection on FCC Form 175 has been published. *See* H Block Report and Order (Revisions to FCC Form 175, OMB Control 3060–0600), Effective Date Notice, published at 78 FR 66287 on November 5, 2013. The revisions to the existing collection on FCC Form 601, OMB Control Number 3060–0798), Effective Date Notice, were published at 79 FR 3133 on January 17, 2014. *See* Notice of Office of Management and Budget Action, ICR Reference Number 201311–3060–018, FCC Application for Radio Service Authorization: WTB and PSHSB, FCC Form 601, OMB Control 3060–0798, Approved without change on Jan. 2, 2014, *available at http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3060-0798#*.

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov <mailto:Cathy.Williams@fcc.gov>*. Please include the OMB Control Number 3060–0800 on correspondence regarding FCC Form 603, and OMB

Control Number 3060–1058 on correspondence regarding the FCC Form 608. The Commission will also accept your comments via email at *PRA@fcc.gov <mailto:PRA@fcc.gov>*.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on January 27, 2014 for revisions to the FCC Forms 603 and 608 to add the national security certification required by § 6004 of the Middle Class Tax Relief and Job Creation Act of 2012, 47 U.S.C 1404. Additionally, the FCC Forms 603 and 608 are revised to update the Alien Ownership certifications pursuant to the Second Report and Order, FCC 13–50, IB Docket 11–133, Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licensees under Section 310(b)(4) of the Communications Act of 1934, as Amended, published at 78 FR 41314–01 on July 10, 2013, *available at http://www.gpo.gov/fdsys/pkg/FR-2013-07-10/pdf/2013-15314.pdf.*

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Numbers are 3060–0800 and 3060–1058. The foregoing notice is required by the Paperwork Reduction Act of 1995, Pub. L. 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0800.

OMB Approval Date: January 27, 2014.

OMB Expiration Date: January 31, 2017.

Title: FCC Application for Assignment of Authorization or Transfer of Control: WTB and PSHS Bureaus.

Form Number: FCC Form 603.

Respondents: Individuals or households, Business or other for-profit entities, not-for-profit institutions, and State, local or tribal government.

Number of Respondents and Responses: 2,447 respondents; 2,447 responses.

Estimated Time per Response: 0.5–1.75 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 4(i), 154(i), 303(r) and 309(j).

Total Annual Burden: 2,754 hours.

Total Annual Cost: $366,975.

Privacy Impact Assessment: Yes.

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: FCC Form 603 is a multi-purpose form used to apply for approval of assignment or transfer of control of licenses in the wireless services. The data collected on this form is used by the FCC to determine whether the public interest would be served by approval of the requested assignment or transfer. This form is also used to notify the Commission of consummated assignments and transfers of wireless and/or public safety licenses that have previously been consented to by the Commission or for which notification but not prior consent is required. This form is used by applicants/licensees in the Public Mobile Services, Personal Communications Services, General Wireless Communications Services, Private Land Mobile Radio Services, Broadcast Auxiliary Services, Broadband Radio Services, Educational Radio Services, Fixed Microwave Services, Maritime Services (excluding ships), and Aviation Services (excluding aircraft).

The purpose of this form is to obtain information sufficient to identify the parties to the proposed assignment or transfer, establish the parties basic eligibility and qualifications, classify the filing, and determine the nature of the proposed service. Various technical schedules are required along with the main form applicable to Auctioned Services, Partitioning and Disaggregation, Undefined Geographical Area Partitioning, Notification of Consummation or Request for Extension of Time for Consummation. The FCC Form 603 is revised to add a National Security Certification that is applicable to applicants for licenses issued pursuant to the Middle Class Tax Relief and Job Creation Act of 2012 (the 2012 Spectrum Act). § 6004 of the 2012 Spectrum Act, 47 U.S.C. 1404, prohibits a person who has been, for reasons of national security, barred by any agency of the Federal Government from bidding on a contract, participating in an auction, or receiving a grant from participating in any auction that is required or authorized to be conducted pursuant to the 2012 Spectrum Act. On June 27, 2013, the Commission released a Report and Order (R&O), FCC 13–88, WT Docket No. 12–357, in which it established service rules and competitive bidding procedures for the 1915–1920 MHz and 1995–2000 MHz bands. *See* Service Rules for the Advanced Wireless Services H Block-Implementing Section 6401 of the Middle Class Tax Relief and Job Creation Act of 2012 Related to the 1915–1920 MHz and 1995–2000 MHz Bands, *Report and Order,* FCC 13–88, 28 FCC Rcd 9483 (2013). The R&O also implemented § 6004 by requiring that a party seeking to participate in any auction conducted pursuant to the 2012 Spectrum Act certify in its application, under penalty of perjury, that the applicant and all of the related individuals and entities required to be disclosed on its application are not person(s) who have been, for reasons of national security, barred by any agency of the Federal Government from bidding on a contract, participating in an auction, or receiving a grant and thus statutorily prohibited from participating in such a Commission auction or being issued a license. In addition, the R&O determined that the National Security Certification required by § 6004 extends to transfers, assignments, and other secondary market mechanisms involving licenses granted pursuant to the 2012 Spectrum Act. *See* H Block R&O, 28 FCC Rcd at 9555 ¶ 187. OMB approved the revision to the collection for the FCC Form 603 to include this additional certification. The revised collection will enable the Commission to determine whether an applicant's request for a license pursuant to the 2012 Spectrum Act is consistent with § 6004.

Additionally, the FCC Form 603 is revised to update the Alien Ownership certifications pursuant to the Second Report and Order, FCC 13–50, IB Docket 11–133, Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licensees under § 310(b)(4) of the Communications Act of 1934, as Amended.

The addition of the National Security Certification and the revision to the Alien Ownership certification resulted in no change in burden for the revised collection.

OMB Control No.: 3060–1058.

OMB Approval Date: January 27, 2014.

OMB Expiration Date: January 31, 2017.

Title: FCC Application or Notification for Spectrum Leasing Arrangement: Wireless Telecommunications Bureau and/or Public Safety and Homeland Security Bureau.

Form No.: FCC Form 608.

Respondents: Business or other for-profit; Not-for-profit institutions; and State, Local or Tribal government.

Number of Respondents and Responses: 991 respondents; 991 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement, Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for collection is contained in 47 U.S.C. 151, 154(i), 154(j), 155, 158, 161, 301, 303(r), 308, 309, 310 and 503.

Total Annual Burden: 991 hours.

Total Annual Cost: $1,282,075.

Privacy Act Impact Assessment: Not applicable.

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: The FCC Form 608 is a multipurpose form. It is used to provide notification or request approval for any spectrum leasing arrangement ('Leases') entered into between an existing licensee ('Licensee') in certain wireless services and a spectrum lessee ('Lessee'). This form also is required to notify or request approval for any spectrum subleasing arrangement ('Sublease'). The data collected on the form is used by the FCC to determine whether the public interest would be served by the Lease or Sublease. The form is also used to provide notification for any Private Commons Arrangement entered into between a Licensee, Lessee, or Sublessee and a class of third-party users (as defined in § 1.9080 of the Commission's Rules).

The FCC Form 608 is revised to add a National Security Certification that is applicable to applicants for licenses issued pursuant to the Middle Class Tax Relief and Job Creation Act of 2012 (2012 Spectrum Act). § 6004 of the 2012 Spectrum Act, 47 U.S.C. 1404, prohibits a person who has been, for reasons of national security, barred by any agency of the Federal Government from bidding on a contract, participating in an auction, or receiving a grant from participating in any auction that is required or authorized to be conducted pursuant to the 2012 Spectrum Act. On June 27, 2013, the Commission released a Report and Order (R&O), FCC 13–88, WT Docket No. 12–357, in which it established service rules and competitive bidding procedures for the 1915–1920 MHz and 1995–2000 MHz bands. *See* Service Rules for the Advanced Wireless Services H Block-Implementing Section 6401 of the Middle Class Tax Relief and Job Creation Act of 2012 Related to the 1915–1920 MHz and 1995–2000 MHz Bands, Report and Order, FCC 13–88, 28 FCC Rcd 9483 (2013). The R&O also implemented § 6004 by requiring that a party seeking to participate in any auction conducted pursuant to the 2012 Spectrum Act certify in its application, under penalty of perjury, that the applicant and all of the related individuals and entities required to be disclosed on its application are not person(s) who have been, for reasons of national security, barred by any agency of the Federal Government from bidding on a contract, participating in an auction, or receiving a grant and thus statutorily prohibited from participating in such a Commission auction or being issued a license. In addition, the R&O determined that the National Security Certification required by § 6004 extends to transfers, assignments, and other secondary market mechanisms involving licenses granted pursuant to the 2012 Spectrum Act. *See* H Block R&O, 28 FCC Rcd at 9555 ¶ 187. OMB approved the revision to the collection for the FCC Form 608 to include this additional certification. The revised collection will enable the Commission to determine whether an applicant's request for a license pursuant to the 2012 Spectrum Act is consistent with § 6004. Additionally, the FCC Form 608 is revised to update the Alien Ownership certifications pursuant to the Second Report and Order, FCC 13–50, IB Docket 11–133, Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licensees under § 310(b)(4) of the Communications Act of 1934, as Amended. The addition of the National Security Certification and the revision to the Alien Ownership certification result in no change in burden for the revised collection. The Commission estimates that the additional certification will not measurably increase the estimated average amount of time for respondents to complete FCC Form 608 across the range of applicants or for Commission staff to review the applications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–02826 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 4 and 12

[PS Docket No. 13–75; PS Docket No. 11–60; FCC 13–158]

Improving 9–1–1 Reliability; Reliability and Continuity of Communications Networks, Including Broadband Technologies

AGENCY: Federal Communications Commission.

ACTION: Correction of effective date.

SUMMARY: The Federal Communications Commission (Commission) is correcting the effective date of a final rule that appeared in the **Federal Register** of January 17, 2014 (79 FR 3123). The document announced the effective date of rules requiring 911 communications providers to take reasonable measures to provide reliable service, as evidenced by an annual certification of conformance with specified best practices or reasonable alternative measures to mitigate the risk of failure. The document also announced the effective date of amendments to the Commission's existing rules requiring certain communications providers to notify public safety answering points (PSAPs) of disruptions in service.

DATES: Effective February 18, 2014, except for the new or modified information collection requirements contained in § 12.4(c), (d)(1), and (d)(3), and § 4.9(h), which have not been approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date.

FOR FURTHER INFORMATION CONTACT: Eric P. Schmidt, Attorney Advisor, Public Safety and Homeland Security Bureau, (202) 418–1214 or *eric.schmidt@fcc.gov*. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Benish Shah, (202) 418–7866, or send an email to *PRA@fcc.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014–00958, appearing on page 3123 in the **Federal Register** of Friday, January 17, 2014, the following corrections are made:

§ 4.9 [Corrected]

■ 1. On page 3123, in the first column, in the DATES section, the text "Effective February 18, 2014, except for § 12.4(c) and (d)(1), which contain information collection requirements that have not been approved by Office of

Management and Budget." is corrected to read "Effective February 18, 2014, except for the new or modified information collection requirements contained in § 12.4(c), (d)(1), and (d)(3), and § 4.9(h), which have not been approved by the Office of Management and Budget."

§ 4.9 [Corrected]

■ 2. On page 3130, in the first and second columns, in paragraph 64, the text "It is further ordered that parts 0, 4, and 12 of the Commission's rules, 47 CFR Parts 0, 4, and 12, are amended, effective February 18, 2014 except for § 12.4(c) and (d)(1), which contain information collection requirements that have not been approved by Office of Management and Budget." is corrected to read "It is further ordered that parts 0, 4, and 12 of the Commission's rules, 47 CFR Parts 0, 4, and 12, are amended, effective February 18, 2014, except for the new or modified information collection requirements contained in § 12.4(c), (d)(1), and (d)(3), and § 4.9(h), which have not been approved by the Office of Management and Budget."

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–02825 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 79

[MB Docket Nos. 12–108, 12–107; FCC 13–138]

Accessibility of User Interfaces, and Video Programming Guides and Menus

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations, which were published in the **Federal Register** of Friday, December 20, 2013 (78 FR 77209). The final regulations divided portions of 47 CFR part 79 improperly. This document correctly divides part 79.

DATES: Effective February 10, 2014. Sections 79.107(c), 79.108(a)(5), 79.108(c) through (e), and 79.110, which were published December 20, 2013 (78 FR 77210), contain information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date for those sections.

FOR FURTHER INFORMATION CONTACT: Adam Copeland, *Adam.Copeland@fcc.gov*, or Maria Mullarkey, *Maria.Mullarkey@fcc.gov*, of the Policy Division, Media Bureau, (202) 418–2120.

SUPPLEMENTARY INFORMATION:

Background

The final regulations divided 47 CFR part 79 into two subparts, Subpart A, consisting of §§ 79.100 through 79.106, and Subpart B, consisting of §§ 79.107 through 79.110. The division improperly omitted pre-existing §§ 79.1 through 79.4. This correction properly divides 47 CFR part 79 into Subpart A, consisting of §§ 79.1 through 79.4, and Subpart B, consisting of §§ 79.100 through 79.110.

Need for Correction

As published, the final regulations improperly omitted existing sections of 47 CFR part 79 and divided part 79 improperly and need to be corrected to remedy these errors.

List of Subjects in 47 CFR Part 79

Cable television operators, Communications equipment, Multichannel video programming distributors (MVPDs), Satellite television service providers.

Accordingly, 47 CFR part 79 is corrected by making the following correcting amendments:

PART 79—ACCESSIBILITY OF VIDEO PROGRAMMING

■ 1. The authority citation for part 79 continues to read as follows:

Authority: 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, 310, 330, 544a, 613, 617.

■ 2. The heading for part 79 is revised to read as set forth above.

■ 3. Transfer §§ 79.1 through 79.4 to subpart A.

■ 4. Transfer §§ 79.100 through 79.106 from subpart A to subpart B.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–02234 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 120918468–3111–02]

RIN 0648–XD120

Fisheries of the Exclusive Economic Zone Off Alaska; Big Skate in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of big skate in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary because the 2014 total allowable catch of big skate in the Central Regulatory Area of the GOA will be reached.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), February 5, 2014, through 2400 hrs, A.l.t., December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2014 total allowable catch (TAC) of big skate in the Central Regulatory Area of the GOA is 1,793 metric tons (mt) as established by the final 2013 and 2014 harvest specifications for groundfish of the GOA (78 FR 13162, February 26, 2013).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2014 TAC of big skate in the Central Regulatory Area of the GOA will be reached. Therefore, NMFS is requiring that big skate caught in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Acting Assistant Administrator for Fisheries, NOAA

(AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of big skate in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 4, 2014.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 5, 2014.

Sean F. Corson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–02822 Filed 2–5–14; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 79, No. 27
Monday, February 10, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 3

[Docket No. APHIS–2012–0106]

Petition To Promulgate Standards for Bears Under the Animal Welfare Act Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition; reopening of comment period.

SUMMARY: We are reopening the comment period for a petition requesting that we amend the Animal Welfare Act regulations to add specific standards for the humane handling, care, treatment, and transportation of all species of bears held in captivity except polar bears, for which there are already standards. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the notice published November 26, 2013 (78 FR 70515) is reopened. We will consider all comments that we receive on or before March 12, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0106-0001.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2012–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0106* or in our reading room, located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Kohn, DVM, Senior Staff Officer, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 851–3751.

SUPPLEMENTARY INFORMATION:

Background

On November 26, 2013, the Animal and Plant Health Inspection Service published in the **Federal Register** (78 FR 70515–70516, Docket No. APHIS–2012–0106) a notice [1] requesting comments on a petition from People for the Ethical Treatment of Animals requesting that we amend the Animal Welfare Act regulations to add specific standards for the humane handling, care, treatment, and transportation of all species of bears held in captivity except polar bears, for which there are already standards.

Comments on the notice were required to be received on or before January 27, 2014. We are reopening the comment period on Docket No. APHIS–2012–0106 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between January 28, 2014 (the day after the close of the original comment period) and the date of this notice.

We encourage the submission of scientific data, studies, or research to support your comments and position, including data or research that supports any industry or professional standards that pertain to the care of bears. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments and recommendations we receive.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02756 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0106.*

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0011; Directorate Identifier 2013–NM–046–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 98–13–23, which applies to certain Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). AD 98–13–23 requires inspections to detect corrosion and cracking of the lower horizontal stabilizer cutout longeron, the corner fitting, the skin strap, and the outer skin; and repair, if necessary. Since we issued AD 98–13–23, we have determined that the risk of cracking is higher than initially determined. This proposed AD would reduce the compliance times and repetitive intervals, and changes the inspection procedures. We are proposing this AD to prevent cracking of the lower horizontal stabilizer cutout longeron, the corner fitting, the skin strap, and the outer skin, which could result in reduced structural integrity of the horizontal-stabilizer cutout longeron.

DATES: We must receive comments on this proposed AD by March 27, 2014.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9

a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0011; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2014–0011; Directorate Identifier 2013–NM–046–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On June 15, 1998, we issued AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998). That AD requires actions intended to address an unsafe condition on the products listed above.

Since we issued AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998), a fleet survey and updated fatigue and damage tolerance analyses showed that the risk of cracks for these airplanes is higher than initially determined. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2013–0048, dated March 4, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> During a full scale fatigue test, a crack was found at the lower corner of the assembly of the horizontal stabilizer cut-out, between Frame (FR)87 and FR89 and between Stringer (STGR)24 and STGR27, Left Hand (LH) and Right Hand (RH) sides.
>
> This condition, if not detected and corrected, could reduce the structural integrity of the aeroplane.
>
> DGAC France issued AD * * * to require repetitive visual and High Frequency Eddy Current (HFEC) rotating probe inspections of the affected areas and subsequent corrective action, in case of cracks.
>
> Since that [DGAC France] AD was issued, a fleet survey and updated Fatigue and Damage Tolerance analyses have been performed to substantiate the second A300–600 Extended Service Goal (ESG2) exercise. The results of these analyses have shown that the risk of cracks for these aeroplanes is higher than initially determined and that, consequently, the thresholds and intervals must be reduced to allow timely detection of these cracks and accomplishment of an applicable corrective action.
>
> For the reasons described above, this [EASA] AD retains the requirements of DGAC France AD * * *, which is superseded, and requires the accomplishment of these actions within the new thresholds and intervals defined in Revision 03 of Airbus Service Bulletin (SB) A300–53–6042 [dated August 30, 2012].

The initial compliance times for airplanes with an average flight time greater than 1.5 hours, depending on the inspection area, are between before 18,000 total flight cycles and 38,100 total flight hours, whichever occurs first; and before 42,500 total flight cycles or 89,000 total flight hours, whichever occurs first. The repetitive compliance times for airplanes with an average flight time above 1.5 hours, depending on the inspection area, are between intervals not to exceed 3,900 flight cycles or 8,200 flight hours, whichever occurs first; and intervals not to exceed 6,000 flight cycles or 12,700 flight hours, whichever occurs first.

The initial compliance times for airplanes with an average flight time of 1.5 hours or less, depending on the inspection area, are between before 19,900 total flight cycles and 29,800 total flight hours, whichever occurs first; and before 47,100 total flight cycles or 70,500 total flight hours, whichever occurs first. The repetitive compliance times for airplanes with an average flight time of 1.5 hours or less, depending on inspection area, are between intervals not to exceed 4,300 flight cycles or 6,400 flight hours, whichever occurs first, and intervals not to exceed 6,600 flight cycles or 9,900 flight hours, whichever occurs first.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0011.

Explanation of Change to Applicability

We have revised the applicability of this AD to identify model designations as published in the most recent type certificate data sheet for the affected models.

Relevant Service Information

Airbus has issued Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

In many FAA transport ADs, when the service information specifies to contact the manufacturer for further instructions if certain discrepancies are found, we typically include in the AD a requirement to accomplish the action using a method approved by either the FAA or the State of Design Authority (or its delegated agent).

We have recently been notified that certain laws in other countries do not allow such delegation of authority, but some countries do recognize design approval organizations. In addition, we have become aware that some U.S.

operators have used repair instructions that were previously approved by a State of Design Authority or a Design Approval Holder (DAH) as a method of compliance with this provision in FAA ADs. Frequently, in these cases, the previously approved repair instructions come from the airplane structural repair manual or the DAH repair approval statements that were not specifically developed to address the unsafe condition corrected by the AD. Using repair instructions that were not specifically approved for a particular AD creates the potential for doing repairs that were not developed to address the unsafe condition identified by the MCAI AD, the FAA AD, or the applicable service information, which could result in the unsafe condition not being fully corrected.

To prevent the use of repairs that were not specifically developed to correct the unsafe condition, certain new requirements of this proposed AD would require that the repair approval specifically refer to the FAA AD. This change is intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we use the phrase "its delegated agent, or the DAH with State of Design Authority design organization approval, as applicable" in this proposed AD to refer to a DAH authorized to approve newly required repairs for this proposed AD.

Costs of Compliance

We estimate that this proposed AD would affect about 5 products of U.S. registry. We estimate the following costs to comply with this proposed AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections [retained actions from AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998].	268 work-hour × $85 per hour = $22,780 per inspection cycle.	$0	$22,780 per inspection cycle.	$45,560 per inspection cycle (2 airplanes)
Inspections [new proposed action]	88 work-hour × $85 per hour = $7,480 per inspection cycle.	0	$7,480 per inspection cycle.	$37,400 per inspection cycle

We estimate the following costs to do any necessary repairs that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair	155 work-hours × $85 per hour = $13,175	$0	$13,175

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998), and adding the following new AD:

Airbus: Docket No. FAA–2014–0011; Directorate Identifier 2013–NM–046–AD.

(a) Comments Due Date

We must receive comments by March 27, 2014.

(b) Affected ADs

This AD supersedes AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998).

(c) Applicability

This AD applies to Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; and Model A300 C4–605R Variant F airplanes; certificated in any

category; on which Airbus Modification 6146 has not been installed.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by reports of cracking found at the lower corner of the horizontal stabilizer cutout longeron during a full scale fatigue test, and a determination that the risk of cracking is higher than initially determined. We are issuing this AD to prevent cracking of the lower horizontal stabilizer cutout longeron, the corner fitting, the skin strap, and the outer skin, which could result in reduced structural integrity of the horizontal-stabilizer cutout longeron.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspections and Corrective Actions

This paragraph restates the requirements of paragraphs (a), (b), (c), (d), and (e) of AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998), with revised service information.

(1) Prior to the accumulation of 18,000 total landings, or within 2,000 landings after July 30, 1998 (the effective date of AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998)), whichever occurs later: Perform a visual and eddy current inspection to detect cracks and/or corrosion of Areas 1 and 2 of the lower horizontal stabilizer cutout longeron, in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. As of the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(2) At the later of the times specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD: Perform a visual and an eddy current inspection to detect cracks and corrosion of Area 3 of the lower horizontal stabilizer cutout longeron, in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. As of the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(i) Prior to the accumulation of 24,000 total landings, but not before the accumulation of 18,000 total landings; or

(ii) Prior to the accumulation of 2,000 landings after July 30, 1998 (the effective date of AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998)).

(3) If no cracking is detected during any inspection required by paragraph (g)(1) or (g)(2) of this AD: Before further flight, cold work and ream the vacated fastener holes, in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012; and perform the requirements of paragraph (g)(3)(i) or (g)(3)(ii) of this AD, as applicable. As of the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(i) For airplanes on which no cracking is found in Area 1 or 2: Repeat the inspections required by paragraph (g)(1) of this AD thereafter at intervals not to exceed 6,000 flight cycles.

(ii) For airplanes on which no cracking is found in Area 3: Perform the various follow-on actions in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. (The follow-on actions include installing a new corner fitting, installing a new longeron, and performing a cold working procedure.) After accomplishment of these follow-on actions, no further action is required by this AD. After the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(4) If any cracking is detected during any inspection required by paragraph (g)(1) or (g)(2) of this AD, perform the requirements of paragraph (g)(4)(i) or (g)(4)(ii) of this AD, as applicable.

(i) If any cracking is found in Area 1 or 3 that is within the limits specified in Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012: Before further flight, repair in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. As of the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(ii) If any cracking is found in Area 2, or if any cracking is found in any area and that cracking is beyond the limits described in Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent, or by the Design Approval Holder (DAH) with EASA design organization approval).

(5) If any corrosion is detected during any inspection required by paragraph (g) of this AD, prior to further flight, repair the corrosion, in accordance with Airbus Service Bulletin A300–53–6042, Revision 1, dated February 20, 1995; or Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. As of the effective date of this AD, use only Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, to do the actions required by this paragraph.

(h) New Inspections

At the applicable times specified in paragraph 1.E., "Compliance," of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, except as provided by paragraph (j)(1) and (j)(2) of this AD: Do the actions specified in paragraphs (h)(1), (h)(2), and (h)(3) of this AD, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. Repeat the inspections, thereafter, at the applicable intervals specified in paragraph 1.E., "Compliance," of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012. Doing the initial inspections required by paragraph (h) of this AD and applicable corrective actions required by paragraph (i) of this AD terminates the requirements of paragraph (g) of this AD.

(1) Do a general visual inspection for cracking and corrosion of the lower horizontal stabilizer cut-out longeron, the corner fitting, the skin strap, and the skin between frame (FR)87 and FR89 and between stringers (STGR)24 and STGR27, left- and right-hand sides.

(2) Do a high frequency eddy current (HFEC) inspection for cracking of the flanges of the lower corner fittings and the edges of the outer skin and the edges of the longeron, the skin strap, and the skin at the run-out of the corner fitting above the last eight fasteners.

(3) Do a rotating probe inspection for cracking of the fastener holes. If no cracking is found during the rotating probe inspection, before further flight, do a cold expansion of the fastener holes, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012.

(i) New Corrective Actions

(1) If any corrosion is found during any inspection required by paragraph (h) of this AD, before further flight, repair, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012.

(2) If any cracking is found during any inspection required by paragraph (h) of this AD, before further flight, repair in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, except where Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, specifies to contact Airbus, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent, or the Design Approval Holder (DAH) with EASA design organization approval). For a repair method to be approved, the repair approval must specifically refer to this AD.

(j) Exception

(1) Where Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, specifies a grace period of 1950 flight cycles or 4100 flight hours, this

AD specifies the grace period after the effective date of this AD.

(2) Where Airbus Mandatory Service Bulletin A300–53–6042, Revision 03, dated August 30, 2012, specifies a compliance time "after receipt of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for the corresponding actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A300–53–6042, Revision 01, dated February 20, 1995; or Airbus Service Bulletin A300–53–6042, Revision 02, dated April 28, 1998; which are not incorporated by reference in this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD. AMOCs approved for AD 98–13–23, Amendment 39–10614 (63 FR 34576, June 25, 1998), are approved as AMOCs for the corresponding requirements of this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the Design Approval Holder with a State of Design Authority's design organization approval, as applicable). You are required to ensure the product is airworthy before it is returned to service.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) Airworthiness Directive 2013–0048, dated March 4, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0011.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 27, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02711 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0004; Directorate Identifier 2013–NM–143–AD]

RIN 2120–AA64

Airworthiness Directives: Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A320–111, –211, –212, and –231 airplanes. This proposed AD was prompted by reports of broken struts of the center wing box (CWB). This proposed AD would require a detailed inspection of the CWB struts for cracking, and repair if necessary. We are proposing this AD to detect and correct cracked or broken struts, which could result in strut failure and consequent reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by March 27, 2014.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0004; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–227–1405; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2014–0004; Directorate Identifier 2013–NM–143–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA

Airworthiness Directive 2013–0149, dated July 16, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Two cases of broken Centre Wing Box (CWB) struts have been reported on A320 aeroplanes. Investigation results indicated that strut thickness in the crack initiation area was lower than specified in the production drawings. Only a limited batch of aeroplanes is affected by this manufacturing defect.
>
> This condition, if not corrected, could result in strut failure, reducing the residual life of the remaining struts to below the initial Design Service Goal, which would deteriorate the structural integrity of the aeroplane.
>
> For the reasons described above, this [EASA] AD requires repetitive Detailed Visual inspections (DVI) of the lower and upper ends of the CWB struts to detect cracks and, depending on findings, accomplishment of associated corrective actions [repair].

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0004.

Relevant Service Information

Airbus has Service Bulletin A320–57–1149, Revision 01, dated February 12, 2013. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

In many FAA transport ADs, when the service information specifies to contact the manufacturer for further instructions if certain discrepancies are found, we typically include in the AD a requirement to accomplish the action using a method approved by either the FAA or the State of Design Authority (or its delegated agent).

We have recently been notified that certain laws in other countries do not allow such delegation of authority, but some countries do recognize design approval organizations. In addition, we have become aware that some U.S. operators have used repair instructions that were previously approved by a State of Design Authority or a Design Approval Holder (DAH) as a method of compliance with this provision in FAA ADs. Frequently, in these cases, the previously approved repair instructions come from the airplane structural repair manual or the DAH repair approval statements that were not specifically developed to address the unsafe condition corrected by the AD. Using repair instructions that were not specifically approved for a particular AD creates the potential for doing repairs that were not developed to address the unsafe condition identified by the MCAI AD, the FAA AD, or the applicable service information, which could result in the unsafe condition not being fully corrected.

To prevent the use of repairs that were not specifically developed to correct the unsafe condition, this proposed AD would require that the repair approval specifically refer to the FAA AD. This change is intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we use the phrase "its delegated agent, or the DAH with State of Design Authority design organization approval, as applicable" in this proposed AD to refer to a DAH authorized to approve required repairs for this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 16 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	12 work-hours × $85 per hour = $1,020 per inspection cycle.	$0	$1,020	$16,320 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition action specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2014–0004; Directorate Identifier 2013–NM–143–AD.

(a) Comments Due Date

We must receive comments by March 27, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A320–211, –212, and –231 airplanes, certificated in any category, all manufacturer serial numbers up to 0136 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by reports of broken struts of the center wing box (CWB) on certain airplanes. We are issuing this AD to detect and correct cracked or broken struts, which could result in struts, which could result in strut failure and consequent reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections

At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD: Do a detailed inspection of each strut of the CWB for cracking, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1149, Revision 01, dated February 12, 2013. Repeat the inspection thereafter at intervals not to exceed 16,800 flight cycles or 33,600 flight hours, whichever occurs first.

(1) For airplanes on which the inspection required by paragraph (g) of this AD has not been done as of the effective date of this AD: Do the inspection at the later of the times specified in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD.

(i) Before the accumulation of 31,700 total flight cycles or 63,400 total flight hours since first flight, whichever occurs first.

(ii) Within 1,250 flight cycles or 2,500 flight hours after the effective date of this AD, whichever occurs first.

(2) For airplanes on which the inspection required by paragraph (g) of this AD has been done as of the effective date of this AD: Do the inspection within 16,800 flight cycles or 33,600 flight hours after the most recent inspection, whichever occurs first.

(h) Repair

If any crack is found during any inspection required by paragraph (g) of this AD: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; the EASA (or its delegated agent, or the Design Approval Holder with EASA's design organization approval). For a repair method to be approved, the repair approval must specifically refer to this AD.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–57–1149, dated April 1, 2008.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–227–1405; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the DAH with a State of Design Authority's design organization approval). You are required to ensure the product is airworthy before it is returned to service.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2013–0149, dated July 16, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0004.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(3) You may view copies of this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 18, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02718 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0009; Directorate Identifier 2013–NM–123–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 707 airplanes, and Model 720 and 720B series airplanes. This proposed AD was prompted by reports of scribe-line-related fatigue cracks on Model 727 airplanes, which are similar in design to Model 707 airplanes, and Model 720 and 720B series airplanes. This proposed AD would require inspections for scribe lines in the skin lap joints, external approved repairs, external features, skin butt joints, and decals, and related investigative and corrective actions if necessary. This proposed AD would also require surface finish restoration. We are proposing this AD to detect and correct scribe lines, which can develop into fatigue cracks in the skin and cause rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by March 27, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room

W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0009; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *Berhane.Alazar@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2014–0009; Directorate Identifier 2013–NM–123–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports of scribe-line-related fatigue cracks on two Model 727 airplanes, which are similar in design to Model 707 airplanes, and Model 720 and 720B series airplanes. One report was on a Model 727–100 airplane with 44,171 total flight cycles. The crack was near a repaired area and caused rapid decompression of the airplane. Another report was on a Model 727–100 airplane with 51,195 total flight cycles. The crack was at station 1090–1110, at the stringer 4L lap joint. This also resulted in rapid decompression of the airplane. Scribe lines could result in fatigue cracks developing in the skin at scribe line locations. Fatigue cracks, if not corrected, could grow large and cause rapid decompression of the airplane.

Related ADs

This proposed AD is similar to the following four ADs, which require inspections to detect scribe lines in the fuselage skin at certain lap joints, around decal locations, external repair doublers, and other areas, and related investigative and corrective actions if necessary. Those ADs resulted from reports of fuselage skin cracks adjacent to the skin lap joints on airplanes that had scribe lines.

• AD 2013–07–11, Amendment 39–17415 (78 FR 22185, April 15, 2013), for certain Boeing Model 777–200, –200LR, –300, and –300ER series airplanes.

• AD 2010–06–16, Amendment 39–16241 (75 FR 12670, March 17, 2010), for certain Boeing Model 767 series airplanes.

• AD 2010–05–13, Amendment 39–16223 (75 FR 10658, March 9, 2010), corrected March 19, 2010 (75 FR 13225) for all Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes.

• AD 2007–19–07, Amendment 39–15198 (72 FR 60244, October 24, 2007), for certain Boeing Model 757–200, –200PF, and –200CB series airplanes.

Relevant Service Information

We reviewed Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA–2014–0009.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information identified previously, except as discussed under "Differences Between the Proposed AD and the Service Information."

The phrase "related investigative actions" is used in this proposed AD. "Related investigative actions" are follow-on actions that: (1) Are related to the primary actions, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

In addition, the phrase "corrective actions" is used in this proposed AD. "Corrective actions" are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between the Proposed AD and the Service Information

Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, specifies to contact the manufacturer for instructions on how to accomplish repairs, but this proposed AD would require repairing those conditions in one of the following ways:

• In accordance with a method that we approve; or

• Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 11 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	96 work-hours × $85 per hour = $8,160	$0	$8,160	$89,760

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2014–0009; Directorate Identifier 2013–NM–123–AD.

(a) Comments Due Date

We must receive comments by March 27, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) All Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; and Model 707–300, –300B, –300C, and –400 series airplanes.

(2) All Model 720 and 720B series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of scribe-line-related fatigue cracks on Model 727 airplanes, which are similar in design to the Model 707 airplanes, and Model 720 and 720B series airplanes. We are issuing this AD to detect and correct scribe lines, which can develop into fatigue cracks in the skin and cause rapid decompression of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Scribe Line Inspection

(1) Except as specified in paragraphs (j)(1) and (j)(2) of this AD, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013: Do a detailed inspection of the fuselage skin for scribe lines, in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013. If no scribe line is found: Before further flight, do surface finish restoration, in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013.

(2) The inspection exceptions described in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, apply to paragraph (g)(1) of this AD.

(h) Related Investigative and Corrective Actions

If any scribe line is found during any inspection required by paragraph (g)(1) of this AD: At the applicable time specified in paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, except as specified in paragraphs (j)(1) and (j)(2) of this AD, do all applicable related investigative and corrective actions, by doing all applicable actions specified in the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, except as specified in paragraph (j)(3) of this AD.

(i) Surface Finish Restoration

After completing any actions required by paragraph (h) of this AD: Before further flight, do surface finish restoration, in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013.

(j) Exceptions to Paragraph (g) of this AD

(1) Where paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, specifies a compliance time "after the original issue date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where the Condition column of paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, refers to total flight cycles "as of the original issue date of this service bulletin," this AD applies to the airplanes with the specified total flight cycles as of the effective date of this AD.

(3) Where Boeing 707 Alert Service Bulletin A3539, dated April 26, 2013, specifies to contact Boeing for additional inspections or repair instructions: Before further flight, repair the scribe line or cracking using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14

CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Related Information

(1) For more information about this AD, contact Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *Berhane.Alazar@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 18, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02717 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0010; Directorate Identifier 2012–NM–218–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Learjet Inc. Model 45 airplanes. This proposed AD was prompted by a report of two cases of premature corrosion found on the structural support flange for the engine thrust reverser. This proposed AD would require doing a fluorescent penetrant inspection of the metallic components of the thrust reverser's attach flange for any corrosion; inspecting the thrust reverser flange for damage to the sealant, as applicable; installing sealants and gaskets, as applicable, to the thrust reverser flanges and service island flanges; and related investigative and corrective actions as necessary. We are proposing this AD to prevent failure of the thrust reverser structural support, which could result in departure of the thrust reverser from the engine that could subsequently result in damage to the adjacent support structure and engine controls, airframe structure, and control surfaces. Departing thrust reversers could also result in injury to persons on the ground.

DATES: We must receive comments on this proposed AD by March 27, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Learjet, Inc., One Learjet Way, Wichita, KS 67209–2942; telephone 316–946–2000; fax 316–946–2220; email *ac.ict@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate; 1601 Lind Avenue SW., Renton, WA 98057–3356. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0010; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Paul Chapman, Aerospace Engineer, Airframe and Services Branch, ACE–118W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: (316) 946–4152; fax: (316) 946–4107; email: *paul.chapman@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2014–0010; Directorate Identifier 2012–NM–218–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received a report of two cases of premature corrosion found on the structural support flange for the engine thrust reverser that attaches the thrust reverser to the engine. The thrust reverser's attach flange is made of aluminum and the corrosion of that flange can be caused by contact with exposed graphite fibers from the engine's composite bypass duct. This condition, if not corrected, could result in failure of the thrust reverser structural support which could result in departure of the thrust reverser from the engine that could subsequently result in damage to the adjacent support structure and engine controls, airframe structure, and control surfaces. Departing thrust reversers could also result in injury to persons on the ground.

Relevant Service Information

We reviewed Bombardier Service Bulletin 40–78–03, Revision 1, dated

November 5, 2012 (for Model 45 airplanes having S/N 45–2001 through 45–2132); and Bombardier Service Bulletin 45–78–9, Revision 1, dated November 5, 2012 (for Model 45 airplanes having S/N 45–005 through 45–436). Those service bulletins describe inspecting the thrust reverser's attach flange for damage to the sealant, as applicable, and installing sealants and gaskets as applicable to the thrust reverser flanges and service island flanges.

We also reviewed Nordam Service Bulletin 5045 78–13, dated January 17, 2012 (for Model 45 airplanes having S/N 45–005 through 45–420 inclusive and S/N 45–2001 through 45–2129 inclusive), which describes procedures for fluorescent penetrant inspection of the metallic components of the thrust reverser's attach flange for any corrosion, and related investigative and corrective actions. Corrective actions include removing corrosion from the thrust reverser's attach flange, applying finishes, contacting the manufacturer, and replacing the engine attach flange. Related investigative actions include doing further fluorescent penetrant inspection for any remaining corrosion, and measuring to ensure a minimum material thickness.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Difference Between the Proposed AD and the Service Information."

Difference Between Proposed AD and the Service Information

Although Nordam Service Bulletin 5045 78–13, dated January 17, 2012, specifies that operators may contact the manufacturer for disposition of certain repair conditions, this proposed AD would require operators to repair those conditions in accordance with a method approved by the FAA.

Costs of Compliance

We estimate that this proposed AD affects 365 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Number of U.S. products	Cost on U.S. operators
Inspections and installing sealants and gaskets.	Between 26 and 36 work-hours × $85 per hour = Between $2,210 and $3,060 per thrust reverser.	Between $1,216 and $1,476 per thrust reverser.	Between $3,426 and $4,536 per thrust reverser.	730 thrust reversers (365 airplanes).	Between $2,500,980 and $3,311,280.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacing thrust reverser attachment flange.	40 work-hours × $85 per hour = $3,400 per thrust reverser.	$1,200 per thrust reverser	$4,600 per thrust reverser.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Learjet Inc.: Docket No. FAA–2014–0010; Directorate Identifier 2012–NM–218–AD.

(a) Comments Due Date

We must receive comments by March 27, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Learjet Inc. Model 45 airplanes having serial numbers (S/N) 45–005 through 45–436 inclusive, and 45–2001 through 45–2132 inclusive, certificated in any category, that are equipped with composite engine fan bypass ducts.

Note 1 to paragraph (c) of this AD: Learjet Model 45 airplanes having S/Ns 45–2001 and subsequent are commonly referred to as Model 40 airplanes or Lear 40 Model 45 airplanes as a marketing designation.

(d) Subject

Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by a report of two cases of premature corrosion found on the structural support flange for the engine thrust reverser. We are issuing this AD to prevent failure of the thrust reverser structural support, which could result in departure of the thrust reverser from the engine that could subsequently result in damage to the adjacent support structure and engine controls, airframe structure, and control surfaces. Departing thrust reversers could also result in injury to persons on the ground.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections and Sealant Installation With Applicable Related Investigative and Corrective Actions

Within 1,200 flight hours or 48 months after the effective date of this AD, whichever occurs first, do the requirements of paragraph (g)(1) of this AD; and for the airplanes identified in paragraph (g)(2) of this AD, do the requirements of paragraph (g)(2) of this AD concurrently.

(1) Do a detailed inspection of the thrust reverser flange for damage to the sealant, as applicable, and install sealants and gaskets before further flight, as applicable, to the thrust reverser flanges and service island flanges, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 40–78–03, Revision 1, dated November 5, 2012 (for Model 45 airplanes having S/N 45–2001 through 45–2132 inclusive); or Bombardier Service Bulletin 45–78–9, Revision 1, dated November 5, 2012 (for Model 45 airplanes having S/N 45–005 through 45–436 inclusive).

(2) For Model 45 airplanes having S/N 45–2001 through 45–2129 inclusive and S/N 45–005 through 45–420 inclusive: Do a fluorescent penetrant inspection for corrosion of the metallic components of the thrust reverser's attach flange for any corrosion, and all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Nordam Service Bulletin 5045 78–13, dated January 17, 2012, except as required by paragraph (h) of this AD. Do all applicable related investigative and corrective actions before further flight.

(h) Exception to the Nordam Service Information

If any material thickness less than the minimum allowable thickness is found during any inspection required by paragraph (g)(2) of this AD, and Nordam Service Bulletin 5045 78–13, dated January 17, 2012, specifies contacting Bombardier Learjet for appropriate action: Before further flight, repair the thrust reverser's attach flange in accordance with a method approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA. For a repair method to be approved by the Manager, Wichita ACO, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 40–78–03, dated February 27, 2012 (for Model 45 airplanes having S/N 45–2001 through 45–2132); or Bombardier Service Bulletin 45–78–9, dated February 27, 2012 (for Model 45 airplanes having S/N 45–005 through 45–436).

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact Paul Chapman, Aerospace Engineer, Airframe and Services Branch, ACE–118W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: (316) 946–4152; fax: (316) 946–4107; email: *paul.chapman@faa.gov.*

(2) For service information identified in this AD, contact Learjet, Inc., One Learjet Way, Wichita, KS 67209–2942; telephone 316–946–2000; fax 316–946–2220; email *ac.ict@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 22, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02715 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0807; Directorate Identifier 2011–NM–191–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for all Airbus Model A318 series airplanes, and Model A319, A320, and A321 series airplanes. The NPRM proposed identifying the part number and serial number of each passenger oxygen container, replacing the oxygen generator manifold of the affected oxygen container with a serviceable manifold, and performing an operational check of the manual mask release, and corrective actions if necessary. The NPRM was prompted by reports of silicon particles inside the oxygen generator manifolds, which had chafed from the mask hoses during installation onto the generator outlets. This action revises the NPRM by adding airplanes to the applicability, adding a new check for part numbers, corrective actions if necessary, and reducing the compliance time for certain actions. We are proposing this AD to detect and correct non-serviceable oxygen generator manifolds, which could reduce or block the oxygen supply and result in injury to passengers when oxygen supply is needed. Since these

actions impose an additional burden over that proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this proposed AD by March 27, 2014.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For Airbus service information identified in this proposed AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com*. For B/E service information identified in this proposed AD, contact B/E Aerospace Systems GmbH, Revalstrasse 1, 23560 Lubeck, Germany; telephone (49) 451 4093–2976; fax (49) 451 4093–4488. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1405; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2012–0807; Directorate Identifier 2011–NM–191–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We proposed to amend 14 CFR part 39 with an earlier NPRM for the specified products, which was published in the **Federal Register** on August 16, 2012 (77 FR 49386). The NPRM proposed to require actions intended to address the unsafe condition for the specified products.

Since the NPRM (77 FR 49386, August 16, 2012) was issued, we have determined that Airbus Model A318–121 and A318–122 airplanes also are affected by the identified unsafe condition of this AD, and therefore we have added them to the applicability paragraph of this AD. We are also making the following changes to the NPRM:

- We have extended the compliance time for certain actions;
- The affected part numbers specified by the NPRM (77 FR 49386, August 16, 2012) have been changed in this supplemental NPRM (SNPRM); and
- A new check for part numbers and a corrective action have been added.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2012–0083, dated May 16, 2012 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> During production of passenger oxygen containers, the manufacturer B/E Aerospace detected some silicon particles inside the oxygen generator manifolds. Investigation revealed that those particles (chips) had chafed from the mask hoses during installation onto the generator outlets. It was discovered that a defective mask hose installation device had caused the chafing.
>
> This condition, if not detected and corrected, could reduce or block the oxygen supply, possibly resulting in injury to passengers when oxygen supply is needed.
>
> To address this potential unsafe condition, EASA issued AD 2011–0167 [(*http://ad.easa.europa.eu/blob/easa_ad_2011_0167_superseded.pdf/AD_2011-0167_1*)] to require the identification and modification of the affected oxygen container assemblies. That AD also prohibited the installation of the affected containers on any aeroplane as replacement parts.
>
> Since that AD was issued, it was established that the Models A318–121 and A318–122 were missing from the Applicability of the AD, and clarification was necessary regarding the affected containers, which are only those marked B/E Aerospace Systems on the equipment data plate.
>
> For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2011–0167, which is superseded, expands the Applicability by adding two aeroplane models, and provides clarity by providing a list of affected passenger oxygen containers.

Required actions also include replacing the oxygen generator manifold of the affected oxygen container with a serviceable manifold, doing an operational check of the manual mask release, and repairing the passenger oxygen container if necessary.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2012–0807.

Comments

We gave the public the opportunity to comment on the NPRM (77 FR 49386, August 16, 2012). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Remove Sentence

Airbus requested that we revise paragraph (h) of the NPRM (77 FR 49386, August 16, 2012) to remove the sentence, "If the operational check fails, before further flight, repair, using a method approved by either the Manager, International Branch, ANM 116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (or its delegated agent)." Airbus explained that the sentence is already covered by instructions for the repair that exist in standard practices.

We disagree with the commenter's request to remove the sentence that specifies accomplishing a repair if an operational test fails. This SNPRM proposes that corrective actions must be done to ensure the identified unsafe condition is addressed. Also, since each

operator may be using different instructions for doing a repair, we cannot reference any particular instructions. We have not changed the SNPRM in this regard.

Request To Correct Typographical Error

Airbus requested that we revise the NPRM (77 FR 49386, August 16, 2012) to correct a typographical error. Airbus explained that the NPRM lists B/E Aerospace Service Bulletin 1XCXX–0100–35–005, Revision 1, dated December 15, 2012, but stated that the date of this service bulletin is December 15, 2011.

We disagree to revise the SNPRM. Airbus has since confirmed that the correct date for B/E Aerospace Service Bulletin 1XCXX–0100–35–005, Revision 1, is December 15, 2012, as referenced in the NPRM (77 FR 49386, August 16, 2012). We have not changed the SNPRM in this regard.

FAA's Determination and Requirements of This Proposed AD

In many FAA transport ADs, when the service information specifies to contact the manufacturer for further instructions if certain discrepancies are found, we typically include in the FAA AD a requirement to accomplish the action using a method approved by either the FAA or the State of Design Authority (or its delegated agent).

We have recently been notified that certain laws in other countries do not allow such delegation of authority, but some countries do recognize design approval organizations. In addition, we have become aware that some U.S. operators have used repair instructions that were previously approved by a State of Design Authority or a Design Approval Holder (DAH) as a method of compliance with this provision in FAA ADs. Frequently, in these cases, the previously approved repair instructions come from the airplane structural repair manual or DAH repair approval statements that were not specifically developed to address the unsafe condition corrected by the AD. Using repair instructions that were not specifically approved for a particular AD creates the potential for doing repairs that were not developed to address the unsafe condition identified by the MCAI AD, the FAA AD, or the applicable service information, which could result in the unsafe condition not being fully corrected.

To prevent the use of repairs that were not specifically developed to correct the unsafe condition, this proposed AD would require that the repair approval specifically refer to the FAA AD. This change is intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we use the phrase "its delegated agent, or the DAH with the State of Design Authority's design organization approval, as applicable" in this proposed AD to refer to a DAH authorized to approve required repairs for this proposed AD.

Certain changes described above expand the scope of the NPRM (77 FR 49386, August 16, 2012). As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 22 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement (The average number of oxygen containers per airplane is 50).	3 work-hours × $85 per hour = $255.	$0	$255	$5,610
Operational Check	3 work-hours × $85 per hour = $255.	0	255	5,610

We estimate the following costs to do any necessary repairs that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair (from operational check)	1 work-hour × $85 per hour = $85	$0	$85
Repair (from part number check of the passenger oxygen container).	1 work-hour × $85 per hour = $85	0	85

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Airbus: Docket No. FAA–2012–0807; Directorate Identifier 2011–NM–191–AD.

(a) Comments Due Date

We must receive comments by March 27, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A318–111, –112, –121, and –122 airplanes; A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; A320–111, –211, –212, –214, –231, –232, and –233 airplanes; A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category; all manufacturer serial numbers (MSN).

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Reason

This AD was prompted by reports of silicon particles inside the oxygen generator manifolds, which had chafed from the mask hoses during installation onto the generator outlets. We are issuing this AD to detect and correct non-serviceable oxygen generator manifolds, which could reduce or block the oxygen supply, which could result in injury to passengers when oxygen supply is needed.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Part Number and Serial Number Identification

Within 5,000 flight cycles, or 7,500 flight hours, or 24 months, whichever occurs first after the effective date of this AD, identify the part number and serial number of each passenger oxygen container. A review of airplane maintenance records is acceptable in lieu of this identification if the part number and serial number of the oxygen container can be conclusively determined from that review.

(h) Replacement, Check, Repair

If the part number of the passenger oxygen container is listed in paragraph (h)(1) of this AD and the serial number of the passenger oxygen container is listed in paragraph (h)(2) of this AD: Within the compliance time specified in paragraph (g) of this AD, do the actions specified in paragraphs (h)(3), (h)(4), and (h)(5) of this AD, except as provided by paragraphs (i)(1) through (i)(7) of this AD.

(1) (Type I: 15 and 22 minutes) 12C15LXXXXX0100, 12C15RXXXXX0100, 13C15LXXXXX0100, 13C15RXXXXX0100, 14C15LXXXXX0100, 14C15RXXXXX0100, 12C22LXXXXX0100, 12C22RXXXXX0100, 13C22LXXXXX0100, 13C22RXXXXX0100, 14C22LXXXXX0100, and 14C22RXXXXX0100; and (Type II: 15 and 22 minutes) 22C15LXXXXX0100, 22C15RXXXXX0100, 22C22LXXXXX0100, and 22C22RXXXXX0100.

Note 1 to paragraph (h)(1) of this AD: The passenger emergency oxygen container assemblies listed in paragraph (h)(1) of this AD are products having the mark "B/E AEROSPACE" on the identification plate.

(2) ARBA–0000 to ARBA–9999 inclusive, ARBB–0000 to ARBB–9999 inclusive, ARBC–0000 to ARBC–9999 inclusive, ARBD–0000 to ARBD–9999 inclusive, ARBE–0000 to ARBE–9999 inclusive, BEBF–0000 to BEBF–9999 inclusive, BEBH–0000 to BEBH–9999 inclusive, BEBK–0000 to BEBK–9999 inclusive, BEBL–0000 to BEBL–9999 inclusive, and BEBM–0000 to BEBM–9999 inclusive.

(3) Replace the oxygen generator manifold of the affected oxygen passenger container with a serviceable manifold, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–35A1047, dated March 29, 2011.

(4) Do an operational check of the manual mask release, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–35A1047, dated March 29, 2011. If the operational check fails, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent, or the Design Approval Holder with EASA's design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD.

(5) Check if the part number of the passenger oxygen container is listed in B/E Aerospace Service Bulletin 1XCXX–0100–35–005, Revision 1, dated December 15, 2012; or B/E Aerospace Service Bulletin 22CXX–0100–35–003, Revision 1, dated December 20, 2011. If the part number is listed in B/E Aerospace Service Bulletin 1XCXX–0100–35–005, Revision 1, dated December 15, 2012; or B/E Aerospace Service Bulletin 22CXX–0100–35–003, Revision 1, dated December 20, 2011; within the compliance time specified in paragraph (g) of this AD, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA (or its delegated agent, or the Design Approval Holder with EASA's design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD.

(i) Exceptions

(1) Oxygen containers that meet the conditions specified in paragraph (i)(1)(i) or (i)(1)(ii) of this AD are compliant with the requirements of paragraph (h) of this AD.

(i) Oxygen containers Type I having a part number listed in paragraph (h)(1) of this AD and having a serial number listed in paragraph (h)(2) of this AD, that have been modified prior to the effective date of this AD, as specified in the Accomplishment Instructions of B/E Aerospace Service Bulletin 1XCXX–0100–35–005, Revision 1, dated December 15, 2012.

(ii) Oxygen containers Type II having a part number listed in paragraph (h)(1) of this AD and having a serial number listed in paragraph (h)(2) of this AD, that have been modified prior to the effective date of this AD, as specified in the Accomplishment Instructions of B/E Aerospace Service Bulletin 22CXX–0100–35–003, Revision 1, dated December 20, 2011.

(2) Airplanes on which Airbus Modification 150703 or Airbus Modification 150704 has not been embodied in production do not have to comply with the requirements of paragraph (h) of this AD, unless an oxygen container having a part number listed in paragraph (h)(1) of this AD and having a serial number listed in paragraph (h)(2) of this AD has been replaced since the airplane's first flight.

(3) Airplanes on which Airbus Modification 150703 or Airbus Modification 150704 has been embodied in production and which are not listed by model and MSN in Airbus Service Bulletin A320–35A1047, dated March 29, 2011, are not subject to the requirements of paragraphs (g) and (h) of this AD, unless an oxygen container having a part number listed in paragraph (h)(1) of this AD and having a serial number listed in

paragraph (h)(2) of this AD has been replaced since the airplane's first flight.

(4) Model A319 airplanes that are equipped with a gaseous oxygen system for passengers, installed in production with Airbus Modification 33125, do not have the affected passenger oxygen containers installed. Unless these airplanes have been modified in-service (no approved Airbus modification exists), the requirements of paragraphs (g) and (h) of this AD do not apply to these airplanes.

(5) Airplanes that have already been inspected prior to the effective date of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–35A1047, dated March 29, 2011, must be inspected and, depending on findings, corrected, within the compliance time defined in paragraph (g) of this AD, as required by paragraph (h) of this AD, as applicable, except as specified in paragraph (i)(6) of this AD.

(6) Airplanes on which the passenger oxygen container has been replaced before the effective date of this AD in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–35A1047, dated March 29, 2011, are compliant with the requirements of the paragraph (h) of this AD for that passenger oxygen container.

(7) The requirements of paragraphs (g) and (h) of this AD apply only to passenger oxygen containers that are Design A, as defined in figure 1 to paragraph (i)(7) of this AD.

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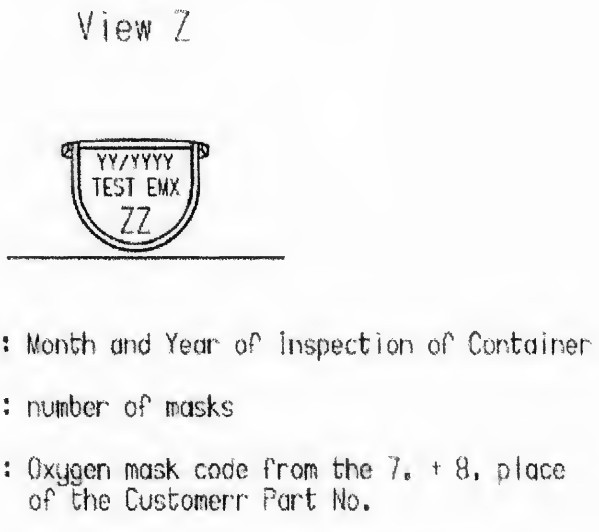
Figure 1 to paragraph (i)(7) of this AD – Design A of the Passenger Oxygen Containers Affected by this AD

Design A: The placard on the passenger oxygen container test button is as described in Picture A of Appendix 1 of this AD. The Mask configuration ("ZZ" in Picture A) is a number and the test button is as shown in Picture B.

Picture A:



Picture B:

Note 1 to figure 1 to paragraph (i)(7) of this AD: Figure 1 to paragraph (i)(7) of this AD contains the information specified in Appendix 1 of EASA Airworthiness Directive 2012–0083, dated May 16, 2012.

(j) Parts Installation Limitations

As of the effective date of this AD, no person may install an oxygen container having a part number specified in paragraph (h)(1) of this AD and having a serial number specified in paragraph (h)(2) of this AD, on any airplane, unless the container has been modified in accordance with the Accomplishment Instructions of any of the service bulletins specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD, as applicable.

(1) Airbus Service Bulletin A320–35A1047, dated March 29, 2011.

(2) B/E AEROSPACE Service Bulletin 1XCXX–0100–35–005, Revision 1, dated December 15, 2012.

(3) B/E AEROSPACE Service Bulletin 22CXX–0100–35–003, Revision 1, dated December 20, 2011.

(k) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (k)(1) or (k)(2) of this AD.

(1) B/E AEROSPACE Service Bulletin 1XCXX–0100–35–005, dated March 14, 2011.

(2) B/E AEROSPACE Service Bulletin 22CXX–0100–35–003, dated March 17, 2011.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1405; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the Design Approval Holder with a State of Design Authority's design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD. You are required to ensure the product is airworthy before it is returned to service.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information European Aviation Safety Agency Airworthiness Directive 2012–0083, dated May 16, 2012, for related information. This may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2012–0807.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* For B/E service information identified in this proposed AD, contact B/E Aerospace Systems GmbH, Revalstrasse 1, 23560 Lubeck, Germany; telephone (49) 451 4093–2976; fax (49) 451 4093–4488. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 21, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–02722 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–13–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA–2014–D–0033]

Draft Guidance for Industry: Demonstration of the Quality Factor Requirements for "Eligible" Infant Formulas; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Guidance for Industry: Demonstration of the Quality Factor Requirements for 'Eligible' Infant Formulas." The draft guidance, when finalized, will describe our current thinking on the quality factor requirements for eligible infant formulas, the record requirements for eligible infant formulas, and the submission of citizen petitions for eligible infant formulas.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 27, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benson M. Silverman, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1459.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for 'Eligible' Infant Formulas." This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The draft guidance is intended to address questions regarding new requirements for eligible infant formulas in § 106.96(i). An interim final rule amending part 106, and establishing the requirements under § 106.96(i), is published elsewhere in this issue of the **Federal Register.**

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's interim final rule on current good manufacturing practices for infant formula published elsewhere in this issue of the **Federal Register**, which this draft guidance is intended to interpret. The proposed collections of information in the interim final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has provided a description of these provisions with estimates of the annual reporting, recordkeeping, and third-party disclosure burden in section IV of the Regulatory Impact Analysis for the interim final rule, entitled "Paperwork Reduction Act of 1995" (Ref. 92 to the interim final rule) and has submitted them for OMB approval.

III. Comments

Interested persons may submit either electronic comments regarding the guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of

comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02731 Filed 2–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA–2014–D–0044]

Draft Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the draft guidance entitled "Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports." The draft guidance, when finalized, will describe our current thinking on the manufacturing of exempt infant formula in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas.

DATES: Although you may comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benson M. Silverman, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1459.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft guidance entitled "Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Audit Procedures, and Records and Reports." Section 412(h)(1) (21 U.S.C. 350a(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) exempts an infant formula which is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as "exempt infant formulas." The draft guidance is intended to describe the significance of the regulations in 21 CFR part 106 for production of exempt infant formulas. Amendments to part 106, in the form of an interim final rule, are published elsewhere in this issue of the **Federal Register.**

We are issuing this draft guidance as Level 1 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on the manufacturing of exempt infant formulas in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports for nonexempt infant formulas in part 106. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register.**

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance and proposed collection of information to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02732 Filed 2–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–0149]

Lohmann Animal Health GMBH; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Lohmann Animal Health GMBH has filed a petition proposing that the food additive regulations be amended to provide for the safe use of the enzyme phytase from bioengineered *Pichia pastoris* yeast in animal feed.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by March 12, 2014.

ADDRESSES: Submit electronic comments to: *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2281) has been filed by Lohmann Animal Health GMBH, Heinz-Lohmann-Strasse 4, 27472 Cuxhaven, Germany. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of the enzyme phytase from bioengineered *Pichia pastoris* yeast in animal feed.

The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(r). Interested persons may submit either electronic or written comments regarding this request for categorical exclusion to the Division of Dockets Management (see **DATES** and **ADDRESSES**). Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–02725 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket ID–OSHA–2007–0066]

RIN 1218–AC86

Cranes and Derricks in Construction: Operator Certification

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: On August 9, 2010, OSHA issued a final standard establishing requirements for cranes and derricks used in construction work. The standard requires employers to ensure that crane operators are certified by November 10, 2014. Until that date, employers also have added duties under the standard to ensure that crane operators are trained and competent to operate the crane safely. The Agency is proposing to extend the deadline for operator certification by three years to November 10, 2017, and to extend the existing employer duties for the same period.

DATES: Submit comments to this proposed rule, including comments to the information-collection (paperwork) determination (described under the section titled "Agency Determinations"), hearing requests, and other information by March 12, 2014. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments, hearing requests, and other material, identified by Docket No. OSHA–2007–0066, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments. Note that this docket may include several different **Federal Register** notices involving active rulemakings, so it is extremely important to select the correct notice or its ID number when submitting comments for this rulemaking. After accessing the docket (OSHA–2007–0066), check the "proposed rule" box in the column headed "Document Type," find the document posted on the date of publication of this document, and click the "Submit a Comment" link. Additional instructions for submitting comments are available from the *regulations.gov* homepage.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (e.g., studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210. These attachments must clearly identify the sender's name, the date, subject, and the docket number (OSHA–2007–0066) so that the Docket Office can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and messenger (courier) service: Submit comments and any additional material to the OSHA Docket Office, RIN No. 1218–AC86, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627). Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The Docket Office will accept deliveries (express delivery, hand delivery, messenger service) during the Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency's name, the title of the rulemaking (Cranes and Derricks in Construction: Operator Certification), and the docket number (i.e., OSHA Docket No. OSHA–2007–0066). OSHA will place comments and other material, including any personal information, in the public docket without revision, and the comments and other material will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the above address. The electronic docket for this proposed rule established at *http://www.regulations.gov* lists most of the documents in the docket. However, some information (e.g., copyrighted material) is not available publicly to read or download through this Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Mr. Frank Meilinger, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *Meilinger.Francis2@dol.gov.*

Technical inquiries: Mr. Vernon Preston, Directorate of Construction, Room N–3468, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2020; fax: (202) 693–1689; email: *Preston.Vernon@dol.gov.*

Copies of this ***Federal Register*** *notice and news releases:* Electronic copies of these documents are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary and Explanation of the Proposed Amendments to the Standard

A. Introduction

OSHA is publishing this Notice of Proposed Rulemaking to extend for three years the employer duty to ensure crane operator competency for construction work, from November 10, 2014, to November 10, 2017. OSHA also is proposing to extend the enforcement date for crane operator certification for three years from November 10, 2014, to November 10, 2017. After publishing the final rule for cranes and derricks in construction, several entities informed OSHA that crane operator certification was insufficient for determining whether an operator could operate their equipment safely on a construction site. After hosting several public meetings discussing this issue, OSHA decided to propose extending the enforcement date for: The employer to ensure competent and safe crane operation; and operator certification. During the three-year extension, OSHA will examine and determine how to address this issue systematically.

B. Summary of Economic Impact

This proposed rule is not economically significant. OSHA proposes to revise 29 CFR 1926.1427(k) (competency assessment and training) to extend the deadline for compliance with the operator-certification requirement in its construction standard for cranes and derricks, and to extend the existing employer duties for the same period. OSHA's preliminary economic analysis shows that extending the date for operator certification and employers' assessment of crane operators, rather than allowing both provisions to expire on November 10, 2014, will result in a net cost savings for the affected industries. Extending the compliance date for operator certification results in estimated cost savings that exceed the estimated new costs for employers to continue to assess crane operators to ensure their competent operation of the equipment in accordance with 1926.1427(k). The detailed preliminary economic analysis is in the "Agency Determinations" section of this preamble.

C. Background

1. Operator Certification Options

OSHA developed the final rule for cranes and derricks in construction (29 CFR subpart CC, referred to as "the cranes standard" hereafter) through a negotiated rulemaking process. OSHA established a federal advisory committee, the Cranes and Derricks Negotiated Rulemaking Advisory Committee (C–DAC), to develop a draft proposed rule. C–DAC met in 2003 and 2004 and developed a draft proposed rule that it provided to OSHA. The rule that OSHA subsequently proposed closely followed C–DAC's draft proposal (73 FR 59718).

The Agency initiated a Small Business Advocacy Review Panel in 2006. The Agency published the proposed rule for cranes in construction in 2008, received public comment on the proposal, and conducted a public hearing. OSHA's final rule incorporated, with minor changes, the four-option scheme C–DAC recommended and the Agency proposed. Accordingly, in § 1926.1427, OSHA requires employers to ensure that their crane operators are certified under at least one of four options by November 10, 2014. The four options are:

Option 1. Certification by an independent testing organization accredited by a nationally recognized accrediting organization;

Option 2. Qualification by an employer's independently audited program;

Option 3. Qualification by the U.S. military; or

Option 4. Compliance with qualifying state or local licensing requirements.

The third-party certification option in § 1926.1427(b)—Option 1—is the only certification option that is "portable," meaning that any employer who employs an operator may rely on that operator's certification as evidence of compliance with the cranes standard's operator certification requirement. This certification option also is the only one that is available to all employers; it is the option that OSHA, and the parties that participated in the rulemaking, believed would be the one most widely used. In this regard, OSHA is not aware of an audited employer qualification program among construction industry employers (Option 2), and the cranes standard limits the U.S. military crane operator certification programs (Option 3) to federal employees of the Department of Defense or the armed services. While state and local governments certify some crane operators (Option 4), the vast majority of operators who become certified do so through Option 1—by third-party testing organizations accredited by a nationally recognized accrediting organization.

Under Option 1, a third party performs testing. Before a testing organization can issue operator certifications, paragraph 1427(b)(1) of the cranes standard provides that a nationally recognized accrediting organization must accredit the testing organizations. To accredit a testing organization, the accrediting agency must determine that the testing organization meets industry-recognized criteria for written testing materials, practical examinations, test administration, grading, facilities and equipment, and personnel. The testing organization must administer written and practical tests that:

- Assess the operator's knowledge and skills regarding subjects specified in the cranes standard;
- provide different levels of certification based on equipment capacity and type;
- have procedures to retest applicants who fail; and
- have testing procedures for recertification.

Paragraph 1427(b)(2) of the final cranes standard also specifies that, for the purposes of compliance with the cranes standard, an operator is deemed qualified to operate a particular piece of equipment only if the operator is certified for that *type and capacity* of equipment or for higher-capacity equipment of that type. It further provides that, if no testing organization

offers certification examinations for a particular equipment type and/or capacity, the operator is deemed qualified to operate that equipment if the operator is certified for the type/capacity of equipment that is most similar to that equipment, and for which a certification examination is available.

2. Overview of § 1926.1427(k) (Phase-In Provision)

The final cranes standard replaced provisions in 29 CFR 1926 subpart N—Cranes, Derricks, Hoists, Elevators, and Conveyors, of the construction safety standards. Provisions for employers to ensure that operators of equipment, including cranes, are trained and qualified to safely operate that equipment are available elsewhere in the construction safety standards (see, for example, § 1926.20(b)(4) and (f)(2)).

OSHA delayed the effective date of the operator certification requirement for four years, until November 10, 2014 (see § 1427(k)(1)). The Agency also wanted to ensure the final cranes standard maintained an employer duty during that four-year "phase-in" period to ensure that crane operators could safely operate equipment (see § 1926.1727(k), *Phase-in.*). Thus, pursuant to § 1926.1427(k)(2)(i), OSHA required employers to "ensure that operators of equipment covered by this standard are competent to operate the equipment safely." Under § 1926.1427(k)(2)(ii), employers must train and evaluate the operator when the operator "assigned to operate machinery does not have the required knowledge or ability to operate the equipment safely".

3. Post-Final Rule Developments

After OSHA issued the final rule, it continued to receive feedback from members of the regulated community and conducted stakeholder meetings on April 2 and 3, 2013, to give interested members of the public the opportunity to express their views. Participants included construction contractors, labor unions, crane manufacturers, crane rental companies, accredited testing organizations, one of the accrediting bodies, insurance companies, crane operator trainers, and military employers. Detailed notes of participants' comments are available at *http://www.osha.gov/cranes-derricks/stakeholders.html* and OSHA–2013–0024–0001. Various parties informed OSHA that, in their opinion, the operator certification option would not adequately ensure that crane operators could operate their equipment safely at a construction site. They said that a certified operator would need additional training, experience, and evaluation, beyond the training and evaluation required to obtain certification, to ensure that he or she could operate a crane safely.

OSHA also received information that two (of a total of four) accredited testing organizations have been issuing certifications only by "type" of crane, rather than by the "type and capacity" of crane, as the cranes standard requires. As a result, those certifications do not meet the standard's requirements and operators who obtained certifications from those organizations cannot, under OSHA's cranes standard, operate cranes on construction sites after November 10, 2014. Some stakeholders in the crane industry requested that OSHA remove the capacity requirement.

Most of the participants in the stakeholder meetings expressed the opinion that an operator's certification by an accredited testing organization did not mean that the operator was fully competent or experienced to operate a crane safely on a construction work site. The participants likened operator certification to a new driver's license, or a beginner's permit, to drive a car. Most participants said that the operator's employer should retain the responsibility to ensure that the operator was qualified for the particular crane work assigned. Some participants wanted certification to be, or viewed to be, sufficient to operate a crane safely. Stakeholders noted that operator certification was beneficial in establishing a minimum threshold of operator knowledge and familiarity with cranes.

D. Explanation of Proposed Action and Request for Comment

The effective dates of the operator certification requirement and the other "phase-in" employer duties are in 29 CFR 1926.1427(k)(1). The Agency is proposing to revise § 1427(k)(1) to extend the deadline for operator certification by three years from November 10, 2014, to November 10, 2017, to provide additional time for the Agency to consider potential rulemaking options. The Agency also is proposing to extend the current employer duties in § 1926.1427(k)(2)(i) and (ii) to ensure that there is no reduction in worker protection during this three-year period. When OSHA included these employer duties in the final cranes standard in 2010, these duties were to be a "phase in" to certification (75 FR 48027). By extending the date as proposed in this notice, the requirements would continue to serve that purpose and preserve the status quo.[1]

As discussed later in this preamble, the Advisory Committee on Construction Safety and Health (ACCSH) recommended postponing certification indefinitely pending further rulemaking and also recommended continuing the existing employer duties for that same period. OSHA seeks comment on this alternative; however, the Agency believes that an indefinite extension would result in complacency in the regulated community because employers may assume that operator certification is not important. Moreover, if the Agency extends the certification deadline indefinitely, it could face additional procedural hurdles in reinstituting the certification requirement, rather than having those requirements take effect automatically at the end of a fixed period.

By extending the enforcement dates by three years, the Agency will have about four years to pursue and complete rulemaking. The Agency is proposing a three-year extension, rather than a shorter period, to give it sufficient time to complete a rulemaking should it choose to do so. The Agency is confident that it can complete a subsequent rulemaking by November, 2017, because: (1) This issue is critical to construction safety and the effectiveness of the final cranes standard, which OSHA previously estimated would prevent 22 fatalities per year (75 FR 47914), and (2) OSHA expects that a subsequent rulemaking would focus on a limited number of discrete issues already debated extensively by stakeholders in the regulated community.

OSHA seeks comment on this approach, including the duration (three years) of the proposed extension of the operator certification deadline and the existing employer duties, as well as the alternative approach recommended by the ACCSH. OSHA encourages commenters to include a rationale for any alternatives that they propose. In addition, OSHA requests comment, data, or information on the potential safety impact of extending operator certification and the current employer duty—or any alternatives. OSHA requests comment on the "Agency

[1] A parallel training requirement in § 1430(c)(2) reiterates the training requirement in paragraph 1427(k)(2), specifying that the training occur during the four-year transition period. OSHA is not proposing to amend § 1430(c)(2) because it believes that amending § 1427(k)(2) is sufficient to extend the relevant employer training duty for employers; however, the Agency welcomes comment on this issue.

Determinations" section that follows, including the preliminary economic analysis, paperwork requirements, and other regulatory impacts of this rule on the regulated community.

II. Agency Determinations

A. Preliminary Economic Analysis and Regulatory Flexibility Analysis

When it issued the final cranes rule, OSHA prepared a final economic analysis (FEA) as required by the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et seq.*) and Executive Orders 12866 (58 FR 51735) (Sept. 30, 1993) and 13563 (76 FR 3821 (Jan. 21, 2011)). OSHA also published a Final Regulatory Flexibility Analysis as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). This preliminary economic analysis (PEA) uses some estimates from these documents.

Because OSHA estimates that this proposed rule will have a cost savings for employers of $21.4 million per year for the three years of the proposed extension, this proposed rule is not economically significant within the meaning of Executive Order 12866, or a major rule under the Unfunded Mandates Reform Act or Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). In addition, this proposed rule complies with Executive Order 13563.

This PEA focuses solely on costs, and not on any changes in safety and benefits resulting from extending the certification deadline and the employer duties under § 1427(k)(2). OSHA previously provided its assessment of the benefits of the cranes standard in the FEA of that standard. As noted elsewhere in this preamble, the primary rationale for proposing the extension is to provide additional time for OSHA to consider the potential costs and benefits of possible adjustments to the operator certification requirements in future rulemaking.

Extending the employer's requirement to ensure an operator's competency during this period means continuing measures in existence since publishing the final crane standard in 2010. As OSHA stated in the preamble to the final rule, the interim measures in paragraph (k) "are not significantly different from requirements that were effective under subpart N of this part at former § 1926.550, § 1926.20(b)(4) ('the employer shall permit only those employees qualified by training or experience to operate equipment and machinery'), and § 1926.21(b)(2) ('the employer shall instruct each employee in the recognition and avoidance of unsafe conditions . . .')" (75 FR 48027).

Delaying the operator certification requirement defers a regulatory requirement and should impose no new costs on employers. There would, however, be continuing employer costs for extending the requirement to assess operators under existing § 1926.1427(k)(2); if OSHA does not extend these requirements, they would expire in 2014 and employers would not incur these costs after 2014. With the extension, these continuing employer costs would be offset by a reduction in expenses that employers would otherwise incur to ensure that their operators are certified before the existing November 2014 deadline.

Overview

In the following analysis, OSHA examined costs and savings to determine the net economic effect of the proposed rule. By comparing the additional assessment costs to the certification cost savings across two scenarios—a scenario in which there is no extension of the 2014 deadline, and a scenario in which there is an extension until 2017—OSHA estimates a net savings for employers of $21.4 million per year, annualized over the 3-year period of the proposed extension using a 7% interest rate ($19.5 million per year using an interest rate of 3%).[2]

OSHA's analysis follows the steps below to reach its estimate of an annual net $21.4 million in savings:

(1) Estimate the annual assessment costs for employers;

(2) Estimate the annual certification costs for employers; and

(3) Estimate the year-by-year cost differential if OSHA extends the certification deadline to 2017.[3]

Table 1 below summarizes these costs and the differentials. In a separate analysis, OSHA examined the cost differential under an alternative to the proposal in which the Agency delays indefinitely the certification deadline and employer-assessment phase out.

a. Annual Assessment Costs

OSHA estimated the annual assessment costs using the following three steps: First, determine the unit costs of meeting this requirement; second, determine the number of assessments that employers will need to perform the assessments in any given year (this determination includes estimating the affected operator pool as a preliminary step); and finally, multiply the unit costs of meeting the requirement by the number of operators who must meet it in any given year to determine the annual costs.

Unit assessment costs. OSHA's unit cost estimates for assessments take into account the time needed for the assessment, along with the wages of both the operator and the specialized operator assessor who will perform the assessment. OSHA based the time requirements on crane operator certification exams currently offered by nationally accredited testing organizations. OSHA determined the time needed for various certification tests from informal conversations the Agency had with industry sources who participated in the public stakeholder meetings. OSHA invites comment on these estimates.

The Agency estimates separate assessment costs for three types of affected operators, which together include all affected operators: Those who have a certificate that is in compliance with the existing cranes standard; those who have a certificate from a nationally accredited testing organization that is not in compliance with the existing cranes standard; and those who have no certificate.[4] OSHA uses certification status as a proxy of competence in estimating the amount of assessment time needed for different operators. OSHA expects that an operator already certified to operate equipment of a particular type and capacity will require less assessment time than an operator certified by type but not capacity, who in turn will require less time than an operator who is not certified. In deriving these estimates, OSHA determined that operators who have a certificate that is compliant with the cranes standard would have to complete a test that is equivalent of the practical part of the standard crane operator test. The

[2] As explained in the following discussion, OSHA typically calculates the present value of future costs and benefits using two interest rate assumptions, 7% and 3%, as recommended by OMB Circular A–4 of September 17, 2003.

[3] For convenience, OSHA refers to the annual time period as a "Certification Year" (CY) in this economic analysis, which OSHA defines as beginning November 10 of the calendar year; e.g., CY 2013 runs from November 10, 2013, to November 9, 2014. There is some small variation in both assessment and certification costs across CYs due to changes in the composition of the operator pool resulting from turnover (discussed below). In this regard, OSHA presents CY 2013 costs in full, and then presents the minor adjustments needed for other CYs.

[4] OSHA is not making any determination about whether a specific certification complies with the requirements of the cranes standard. For the purposes of this analysis only, OSHA will treat certificates that do not include a capacity component as not complying with the cranes standard, and certificates that include both a type and capacity component as complying with the cranes standard.

Agency estimates that it would take an operator one hour to complete this test. Operators who have a certificate that is not in compliance with the cranes standard would have to complete a test that is equivalent to both a written general test and a practical test of the standard crane operator test. OSHA estimated that the written general test would take 1.5 hours to complete, for a total test time of 2.5 hours of testing for each operator (1.5 hours for the written general test and 1.0 hour for the practical test). Finally, operators with no certificate would have to complete a test that is equivalent to the written test on a specific crane type of the standard crane operator test (also lasting 1.5 hours), as well as the written general test and the practical test, for a total test time of 4.0 hours (1.5 hours for the test on a specific crane type, 1.5 hours for the written general test, and 1.0 hour for the practical test).

The wages used for the crane operator and assessor come from the final cranes rule (75 FR 48102). Accordingly, the operator wage is $35.62, while the wage of the assessor is estimated to be the same as the wage of a crane inspector, $41.25. For assessments performed by an employer of a prospective employee (i.e., a candidate), OSHA used these same operator and assessor wages and the above testing times to estimate the cost of assessing prospective employees.

Multiplying the wages of operators, assessors, and candidates by the time taken for each type of assessment provides the cost for each type of assessment. Hence, the cost of assessing an operator already holding a certificate that complies with the standard (both type and capacity) is one hour of both the operator's and assessor's time: $76.87 ($35.62 + $41.25). For an operator with a certificate for crane type only (not crane capacity), the assessment time is 2.5 hours for a cost of $192.18 (2.5 × ($35.62 + $41.25)). Finally, for an operator with no certificate, the assessment time is 4.0 hours for a cost of $307.48 (4.0 × ($35.62 + $41.25)).

Besides these assessment costs, OSHA notes that § 1427(k)(2)(ii) requires employers to provide training to employees if they are not already competent to operate their assigned equipment. To determine whether an operator is competent, the employer must first perform an assessment. Only if an operator fails the assessment will the operator require training. However, in determining this cost, OSHA made a distinction between a nonemployee candidate for an operator position and an operator who is currently an employee. For an employer assessing a nonemployee candidate, OSHA assumed, based on common industry practice, that the employer will not hire a nonemployee candidate who fails the assessment. In the second situation, an employee qualified to operate a crane fails a type and/or capacity assessment for a crane that differs from the crane the employee currently operates. In this situation, the cost-minimizing action for the employer is not to assign the employee to that type and/or capacity crane, thereby avoiding training costs. While the Agency acknowledges that there will be cases in which the employer will provide this training, it believes these costs to be minimal and, therefore, is not taking costs for the training.

Number of assessments and number of affected operators. The number of assessments is difficult to estimate due to the heterogeneity of the crane industry. Many operators work continuously for the same employer, already have their assessment, and do not need reassessment, so the number of new assessments required by the cranes standard for these operators will be zero. Some crane companies will rent both a crane and an operator employed by the rental company to perform crane work, in which case the rental crane company is the operator's employer and responsible for operator assessment. In such cases there is no need for the contractor who is renting the crane service to conduct an additional operator assessment. Assuming that employers already comply with the assessment and training requirements of the existing § 1427(k)(2), employers only need to assess a subset of operators: New hires; employees who will operate equipment that differs by type and/or capacity from the equipment on which they received their current assessment; and operators who indicate that they no longer possess the required knowledge or skill necessary to operate the equipment.

To calculate the estimated annual number of assessments, OSHA first estimated the current number of crane operators affected by the cranes standard. The FEA in the final cranes standard identified a total of 142,630 affected crane operators (75 FR 48108). However, after publishing the final cranes standard, OSHA made revisions to the cranes standard that reduced the total number of affected operators. In this regard, OSHA excluded a significant percentage of digger-derrick use from the scope of the cranes standard (see Cranes and Derricks in Construction: Revising the Exemption for Digger Derricks, 78 FR 32110 (May 29, 2013)). Accordingly, for electric power generation and transmission work covered by the digger-derrick exemption, OSHA found that the two industries using digger derricks have a total of 25,500 operators for both digger derrick and other covered equipment; these industries are: Electric Power Generation, NAICS: 221110; and Electric Power Transmission, NAICS: 221120; see 78 FR 32114). Subtracting these digger-derrick operators from the original total leaves the total number of operators affected by this proposal at 117,130 (i.e., 142,630 − 25,500).

For the purpose of determining the number of assessments required each year under this proposal, OSHA is relying on the original 23% turnover rate for operators identified in the 2008 PEA for the cranes rule (73 FR 59895), which includes all types of operators who would require assessment: Operators moving between employers; operators moving between different types and/or capacities of equipment; and operators entering the occupation. OSHA estimated that 26,940 assessments occur each year based on turnover (i.e., 117,130 operators × 0.23 turnover rate). This number includes assessments performed by an employer on current employees assigned to a new type and/or capacity crane. In addition, OSHA in the 2008 PEA assumed that 15% of operators involved in assessments related to turnover would fail the first test administration and need reassessment (73 FR 59895). Therefore, in this proposal, OSHA is adding 4,041 reassessments (i.e., 26,940 operators × 0.15) to the number of reassessments resulting from turnover, for a total of 30,981 yearly assessments resulting from turnover and test failure (i.e., 26,940 + 4,041).

Annual assessment costs. Annual assessment costs will vary by year depending on several factors; the following section addresses year-by-year variations. However, OSHA must first determine the annual base amount from which to account for the variations, and must do so for the two scenarios: (1) Retaining the deadline specified by the existing cranes standard (status quo); and (2) extending the deadline to 2017 (proposed rule).

The first part of the calculation is the same under both scenarios. Because the annual assessment costs vary by the different levels of assessment required (depending on the operator's existing level of certification), OSHA grouped the 117,130 operators subject to the cranes standard into three classifications: Operators with a certificate that complies with the standard; operators with a certificate only for crane type; and operators with

no certification. From discussions with members of the crane industry, OSHA estimated that 15,000 crane operators currently have a certificate that complies with the existing cranes standard, and another 60,000 have a certificate for crane type only (but not capacity). Therefore, 42,130 crane operators have no crane certification (i.e., 117,130 total operators − (15,000 operators with compliant certification + 60,000 operators with certification for type)).

Assuming the turnover rate of 23% and the failure rate of 15% for turnover-related assessments are distributed proportionally across the three types of operators, then the number of assessments for operators with compliant certification is 3,968 (i.e., $(0.23 + (0.23 \times 0.15)) \times 15{,}000$), the number of assessments for operators with type-only certification is 15,870 (i.e., $(0.23 + (0.23 \times 0.15)) \times 60{,}000$), and the number of assessments for operators with no certification is 11,143 (i.e., $(0.23 + (0.23 \times 0.15)) \times 42{,}130$). Under scenario 2 (employer-assessment requirement extended to 2017), OSHA estimated the CY 2013 costs by multiplying the assessment numbers for each type of operator by the unit costs, resulting in a cost of $6,781,167 (i.e., $(\$76.87 \times 3{,}968) + (\$192.18 \times 15{,}870) + (\$307.48 \times 11{,}143)$). Under scenario 1, employers would be certifying operators throughout CY 2013, whereas under scenario 2 employers would be deferring the certifications until CY 2016; as a result, the CY 2013 assessment costs for scenario 1 would decrease from $6,781,167 to $4,581,334 because a percentage of the operators under scenario 1 will obtain a compliant certificate before they are assessed, thereby reducing the time and cost needed for the assessment (see discussion of year-by-year cost differential in section c below for more details about this determination).

b. Annual Certification Costs

OSHA estimated the annual certification costs using the three steps used for estimating annual assessment costs: First, determine the unit costs of meeting this requirement; second, determine the number of affected operators; and, finally, multiply the unit costs of meeting the requirement by the number of operators who must meet them. For the proposed extension, OSHA estimated that almost all certification will occur in the year prior to the deadline. OSHA notes that although the current November 2014 deadline is just over a year away, there is evidence that the vast majority of operators do not yet have certification that is in compliance with the existing standard. Based upon this evidence, if OSHA extends the existing requirements to November 2017, OSHA estimates that the vast majority of employers will again wait until the year before the deadline (i.e., CY 2016) to certify all operators. As in the annual assessment-cost analysis described above, OSHA provides the calculations for CY 2013 under the 2014 deadline specified by the existing cranes standard (scenario 1), and then presents the certification costs for CY 2016 that would apply if OSHA extends the certification requirement to November 2017 (scenario 2).

Unit certification costs. Unit certification costs vary across the three different types of operators in the operator pool (operators with compliant certification; operators with type-only certification; and operators with no certification). Among operators without certification there is a further distinction with different unit certification costs: Experienced operators without certification and operators who have only limited experience. Therefore, there are different unit certification costs for four different types of operators. There also are ongoing certification costs due to the following three conditions: The five-year limit on operator certification; the need for some certified operators to obtain additional certification to operate a crane that differs by type and/or capacity from the crane on which they received their current assessment; and a yearly 5% turnover rate (i.e., 5% new crane operators entering the occupation to replace operators leaving the occupation).

OSHA estimated these different unit certification costs using substantially the same unit-cost assumptions from the FEA. In the FEA, OSHA estimated that training and certification costs for an operator with only limited experience would consist of $1,500 for a 2-day course (including tests) and 18 hours of the operator's time, for a total cost of $2,141.16 (i.e., $1,500 + (18 hours × $35.62)) (see 75 FR 48096). OSHA continues to use a cost of $250 for the tests taken without any training (a constant fixed fee irrespective of the number of tests (75 FR 48096)), and the same number of hours used for each test that it used in the assessment calculations provided above (which the Agency based on certification test times). Accordingly, OSHA estimated the cost of a certificate compliant with the standard for an operator who has a type-only certificate to be $339.05 (i.e., 1 type/capacity-specific written test at 1.5 hours and 1 practical test at 1.0 hours (2.5 hours total), plus the fixed $250 fee for the tests (i.e., (2.5 hours × $35.62) + $250). For an experienced operator with no certificate, the cost is $392.48 (i.e., the same as the cost for an operator with a type-only certificate plus the cost of an added general written test of 1.5 hours (i.e., (4.0 hours × $35.62) + $250).[5]

The cranes standard under Option 1 (the standard case) of § 1926.1427(b)(4) specifies that a certificate is valid for five years. OSHA estimates the recertification unit cost would be the same as the assessment for an operator with compliant certification (i.e., $76.87).

Finally, there will be certified operators who must obtain certification when assigned to a crane that differs by type and/or capacity from the crane on which they received their current assessment. This situation requires additional training, but less training than required for a "new" operator with only limited experience. Accordingly, OSHA estimated the cost for these operators as one half of the cost of training and certifying a new operator, or $1,070.08 (i.e., $2,141.16 ÷ 2).

Number of certifications. After establishing the unit certification costs, OSHA had to determine how many certifications are necessary to ensure compliance with OSHA's standard. In doing so, the Agency uses the 5% new-hire estimate from the FEA discussed above to calculate the number of new operators; therefore, of the 117,130 operators affected by the proposed standard, 5,857 (i.e., $0.05 \times 117{,}130$) would be new operators who would require two days for training and certification each year. As discussed earlier, OSHA estimated that 60,000 operators have type-only certification, and 15,000 operators have certification that complies with the existing cranes standard. The remaining 36,274 operators (i.e., 117,130 − (60,000 + 15,000 + 5,857)) are experienced operators without certification.

After all operators attain certification by the proposed deadline, there will still be ongoing certification costs each year. OSHA estimated that 5% of all operators each year, or 5,857 (i.e., .05 × 117,130), are new operators with no experience or certification and, therefore, will need an initial certification. Consequently, with a constant total number of operators, the same number of operators (5,857) will be leaving the occupation each year and will not require recertification when

[5] There are no certification costs for operators who already have a certificate that complies with the cranes standard.

their current 5-year certification ends. This leaves 111,274 operators (i.e., 117,130 − 5,857) who will need such periodic recertification. If we approximate the timing of requirements for recertification as distributed proportionally across years, then 20% of all operators with a 5-year certificate (i.e., 22,255 operators (.20 × 111,274)) would require recertification each year. A final category of unit certification costs involves the continuing need for certified operators to obtain further certification when assigned to a crane that differs by type and/or capacity from the crane on which they received their current assessment. This situation arises for both operators working for a single employer and operators switching employers. The 23% turnover rate from the cranes PEA covers pre-deadline situations in which an operator needs an assessment, and also situations in the post-deadline period in which an operator needs multiple certifications. The operators requiring assessments in the pre-deadline period who will not need additional certification in the post-deadline period are operators with certification who move to a new employer and operate a crane with the same type and capacity as the crane on which they received certification from their previous employer. These operators will not need reassessment because of the portability of an operator certificate across employers specified by the cranes standard (see § 1427(b)(3)). For an employer looking to hire an operator for a specific crane, this option will minimize cost, and OSHA assumes employers will choose this option when possible.

After the certification deadline, OSHA estimates that each year 23% of the 117,130 operators (26,940, i.e., 0.23 × 117,130) will enter the workforce, change employers, or take on new positions that require one or more additional certifications to operate different types and/or capacities of cranes. Of these 26,940 operators, OSHA estimates that 5% of that turnover, or 5,857 ((i.e., 0.05 × 117,130), will result from new operators entering the occupation each year; 9%, or 10,542 (i.e., 0.09 × 117,130), will result from operators switching employers but operating a crane of the same type and capacity as the crane they operated previously (i.e., no certification needed because certification is portable in this case); and the remaining 9%, or 10,542, changing jobs or positions and requiring one or more additional certification to operate a crane that differs by type and/or capacity from the crane they operated previously.

Annual certification costs. As with the assessment costs, certification costs will vary by year depending on several factors addressed in the following section. However, OSHA still needs to determine the annual base amount from which to account for the variations, and must do so for the same two scenarios: (1) Retaining the deadline specified by the existing cranes standard (status quo); and (2) extending the deadline to 2017 (proposed rule).

To estimate the annual base cost for the first scenario, OSHA calculates the certification costs for CY 2013 because that is the remaining period before the deadline specified by the existing cranes standard. The total cost for certifying all operators in CY 2013 in accordance with the above unit-cost estimates and numbers of operators is $47,119,327 (i.e., (60,000 operators with type-only certification × $339.05) + (36,274 experienced operators without certification × $392.48) + (5,857 operators with no experience or certification × $2,141.16)). The Agency, following the FEA (75 FR 48096), annualized this cost for the five-year period during which operator certification remains effective, resulting in an annualized cost of $8,433,648. In section c below, OSHA uses this amount in calculating the annual certification costs under scenario 1.

To determine the annual amount used in calculations for the second scenario (the proposed extension to 2017), OSHA examines the costs in CY 2016 because that is the first year with certification costs (as noted earlier, OSHA determined that, under the proposed extension, employers will postpone certification costs until CY 2016, so there will not be any new certification costs for CY 2013–2015). Using the same methodology used to calculate the CY 2013 certification costs, the total cost for having all crane operators certified in CY 2016 is $48,416,216 (in 2016 dollars). The annualized cost over the five-year period during which certification remains effective is $8,749,948. In the following section, OSHA uses this amount in calculating the annual certification costs under scenario 2.

c. Year-by-Year Cost Differential If OSHA Extends the Certification Deadline to 2017

The ultimate goal of this analysis is to determine the annual cost differential between scenario 1 (the status quo) and scenario 2 (the proposed rule), so the final part of this PEA compares the yearly assessment and certification costs employers will incur for the two scenarios. Because the assessment and certification costs change each year under each scenario, OSHA must compare the cost differential in each year separately to determine the annual cost savings for each year attributable to adopting scenario 2. OSHA calculated the present value of each year's differential, which provides a consistent basis for comparing the cost differentials over the extended compliance period. OSHA then annualized the present value of each differential to identify an annual amount that accounts for the discounted costs over this period. Table 1 below summarizes these calculations.

Table 1 shows that assessment and certification costs vary each year under scenario 2. There are several factors that cause these costs to vary: (1) The five-year limit on operator certification causes some operators to require recertification during this period; (2) the need for some certified operators to obtain additional certification to operate a crane that differs by type and/or capacity from the crane on which they received their current assessment; and (3) the yearly 5% turnover that results in new crane operators entering the occupation. In addition, the composition of the operator pool will shift in the year before the deadline because a higher share of all operators will have certification. This shift would decrease the need to perform a longer and more costly assessment, thereby reducing the high costs associated with operators who do not have certification (i.e., employers would take less time assessing operators with compliant certification in this certification year compared to years in which there is no deadline). To account for this effect, OSHA adjusted assessment costs in the year directly preceding the deadline in each scenario (i.e., CY 2013 for scenario 1 and CY 2016 for scenario 2).

Accordingly, OSHA determined that assessment costs for CY 2013 under the first scenario would decrease from $6,781,167 under scenario 2 to $4,581,334 under scenario 1 because of the increasing certification effect that occurs near the deadline.[6] A similar

[6] OSHA estimates that operators will obtain their compliant certification at a uniform rate throughout the certification year immediately preceding the deadline, which implies that certification costs can be estimated by using a weighted average of the unit costs if no operators become compliant certified, and the unit costs if all operators are so certified, with equal weight attributed to each condition (i.e., each condition (no operators and all operators) contributing one half to the estimate). The Agency then values assessment unit costs as if none of the operators had certification, which would result in maximum assessment times, with unit costs determined by total costs divided by total assessments, which is $218.18 (i.e., $6,781,167 total

Continued

calculation for CY 2016 (the year prior to the proposed certification deadline in 2017) lowers the estimated assessment costs from $7.2 million (in the absence of the deadline and accompanying certification) to $4.8 million under scenario 2.

One-time costs for certifying operators with non-compliant certification ($20,343,000) and certifying experienced operators with no certification ($14,236,623) account for much of the rise in certification costs in CY 2013 under scenario 1. OSHA annualized these one-time operator certification costs across CY 2013–2017 (matching the 5-year duration of the certifications received in the last year before the deadline), resulting in an annualized cost of $8,433,648 for each year of this five-year period under scenario 1.[7] Under scenario 2, the corresponding annualized certification costs for CY 2016–2020 (again matching the 5-year duration of the certifications received in the last year before the deadline) would be $8,749,948. The certification costs vary in the other (pre-deadline) years depending on factors identified earlier in this PEA.

As noted earlier, OSHA estimated the overall cost differential between these two scenarios by calculating the difference in total (assessment and certification) costs each year across the two scenarios. The net employer cost savings in current dollars attributable to adopting the second scenario are, for each certification year: 2013, $18.8 million; 2014, $27.1 million; 2015, $26.9 million; 2016, $7.9 million; 2017, −$0.3 million; 2018, −$8.7 million; 2019, −$8.7 million; and 2020, −$8.7 million.[8]

TABLE 1—YEAR-BY-YEAR COST DIFFERENTIAL IF OSHA EXTENDS THE CERTIFICATION DEADLINE TO 2017

	2013	2014	2015	2016	2017	2018	2019	2020	2021
Operator Pool									
Scenario 1 (no deadline extension):									
Operators with type-only certification	60,000	0	0	0	0	0	0	0	0
Operators with complaint certification	15,000	111,274	111,274	111,274	111,274	111,274	111,274	111,274	111,274
Operators with no certification	36,274	0	0	0	0	0	0	0	0
New operators	5,857	5,857	5,857	5,857	5,857	5,857	5,857	5,857	5,857
Scenario 2 (deadline extension):									
Operators with type-only certification	60,000	57,000	54,150	51,443	0	0	0	0	0
Operators with compliant certification	15,000	14,250	13,538	12,861	111,274	111,274	111,274	111,274	111,274
Operators with no certification	36,274	40,024	43,586	46,970	0	0	0	0	0
New operators	5,857	5,857	5,857	5,857	5,857	5,857	5,857	5,857	5,857
Costs									
Scenario 1 (no deadline extension):									
Total assessment costs	$4,581,334	0	0	0	0	0	0	0	0
Total certification costs	20,973,352	$33,969,804	$33,969,804	$33,969,804	$33,969,804	$25,536,156	$25,536,156	$25,536,156	$25,536,156
Total	25,554,686	33,969,804	33,969,804	33,969,804	33,969,804	25,536,156	25,536,156	25,536,156	25,536,156
Scenario 2 (deadline extension):									
Total assessment costs	6,781,167	6,918,409	7,048,788	4,777,075	0	0	0	0	0
Total certification costs	0	0	0	21,289,651	34,286,103	34,286,103	34,286,103	34,286,103	25,536,156
Total	6,781,167	6,918,409	7,048,788	26,066,726	34,286,103	34,286,103	34,286,103	34,286,103	25,536,156
Cost Differential (Scenario 2 − Scenario 1)	(18,773,519)	(27,051,395)	(26,921,015)	(7,903,078)	316,299	8,749,948	8,749,948	8,749,948	0

Source: OSHA, ORA Calculations.

OSHA next determined the present value of these cost differentials between the two scenarios. OSHA calculated the present value of future costs using two interest rates assumptions, 7% and 3%, which are the rates OSHA used in the FEA of the cranes standard (75 FR 48080), and which follow the OMB guidelines specified by Circular A–4 of September 17, 2003. At an interest rate of 7%, the present value of the cost differentials for CY 2013 onwards results in an estimated savings of $56.3 million ($55.2 million using the 3% rate). Finally, annualizing the present value over the proposed three-year extension period results in an annualized cost differential (i.e., net employer cost savings) of $21.4 million per year ($19.5 million per year using the 3% rate).

d. Alternative: Indefinite Extension of the Certification Deadline

As noted above, ACCSH recommended that OSHA extend indefinitely the deadline for operator certification and the employer duties under § 1427(k)(2). OSHA is requesting comment on this alternative, and is providing the following analysis of potential employer costs and savings under this alternative. Based on the calculations described above, cost savings under this alternative would be larger than the cost savings under the proposed 2017 extension because there would be no rise in certification costs later in the extension period.

This alternative would result in an indefinite extension of employer assessments and associated costs. Assuming that no operator would have any type of certification, all assessments would involve the 4-hour assessment at a cost of $307.48. Thus, using the same estimates of 23% turnover and a 15% failure rate described above, the yearly

assessment cost ÷ 30,981 total yearly assessments). OSHA next values unit assessment costs as if all operators had compliant certification, which would require the shortest assessment time of 1 hour, and a cost of $76.87. The ratio of the second unit assessment cost to the first unit assessment cost is .35 ($76.87 ÷ $218.88). Therefore, the resulting assessment cost in CY 2013 using the weighted average formula is $4,581,334 (i.e., (0.5 × $6,781,167) + (0.5 × 0.35 cost ratio × $6,781,167).

[7] Under scenario 1, therefore, the total certification costs of $33,969,804 for each year over CY2014–2017 consist of the annualized cost of $8,433,648 for the one-time operator certification costs and $25,536,156 for fixed costs involving recertification of compliant operators, additional certifications for operators changing type or capacity of crane, and certification of new operators.

[8] A positive cost differential indicates net savings and a negative cost differential indicates net costs. Savings in earlier years results largely from the extension of the certification deadline. The cost differential then turns negative in later years largely because employers complete certification under the first scenario while they are just beginning certification under the second scenario.

By 2017, under both scenarios all existing operators will have compliant certification. However, under the second scenario, the five-year annualization of when certification costs are incurred would continue until 2020. Hence, 2021 is the first year when, under both scenarios, employer costs would consist solely of ongoing certification costs, and the cost differential between the two scenarios would be zero. The ongoing certification costs consist of: the yearly cost resulting from new operators (5% of all operators) entering the operator pool; the proportion of the pool that must receive recertification each year resulting from expiration of the five-year certification; and the annual additional certifications that occur.

assessment costs would be $9,526,003 (0.23 × 1.15 × 117,130 × $307.48) for this alternative.

While assessment costs would disappear after the deadline under any scenario with a specified certification deadline, there will still be annual ongoing employer certification costs for new operators, as well as recertifications and additional certifications for operators previously certified. As noted earlier, total yearly ongoing certification costs consist of: 5% new operators each year with certification costs of $2,141.16 for each operator, or $12,539,704 total (0.05 × 117,130 × $2,141.16); recertification of 20% of the previously certified operator pool at a cost of $76.87 for each operator, or $1,710,719 total (0.20 × 0.95 × 117,130 × $76.87); and 9% of the operator pool getting additional certification at a unit cost of $1,070.58 for each operator, or $11,285,733 total (0.09 × 117,130 × $1,070.58). Adding these costs, the grand total each year post-deadline for scenarios with specified certification deadlines is $25,536,156 ($12,539,704 + $1,710,719 + $11,285,733). Hence, even without considering the upfront costs of having all current operators certified to the standard, postponing the certification deadline indefinitely would result in a net yearly savings of $16,010,153 ($25,536,156 − $9,526,003) each year. Therefore, the ACCSH-recommended alternative would increase cost savings by removing the additional cost associated with having to fully certify, and maintain certification for, the total operator pool by a specified deadline.

e. Certification of No Significant Impact on a Substantial Number of Small Entities

Because the Agency estimates the cost of any single assessment to be no higher than $307.48, it believes the economic impact would be minimal on any employer. Most employers would have savings resulting from the three-year extension, particularly employers that planned to pay for operator certification in the year before the deadline specified by the existing cranes standard. The only entities likely to see a net cost would be entities that planned to hire an operator with compliant certification after November 10, 2014. Without the proposed extension, these entities would have no separate assessment duty, but under the proposed extension they would have the expense involved in assessing operator competency. As noted above, however, OSHA estimated the cost for such assessments (for operators with a type and capacity certification) to be $76.87 per certified operator.

Small businesses would, by definition, have few operators, and OSHA believes the $76.78 cost would be well below 1% of revenues, and well below 5% of profits, in any industry sector using cranes. OSHA does not consider such small amounts to represent a significant impact on small businesses in any industry sector. Hence, OSHA certifies this proposed rule would not have a significant impact on a substantial number of small entities. OSHA invites comments on this certification and the underlying rationale.

B. Paperwork Reduction Act of 1995

When OSHA issued the final rule on August 9, 2010, it submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) titled *Cranes and Derricks in Construction (29 CFR Part 1926, Subpart CC)*.[9] On November 1, 2010, OMB approved the ICR under OMB Control Number 1218–0261, with an expiration date of November 30, 2013. Subsequently, in December 2010, OSHA discontinued the *Cranes and Derricks Standard for Construction (29 CFR 1926.550)* ICR (OMB Control Number 1218–0113) because the new ICR superseded the existing ICR. In addition, OSHA retitled the new ICR to *Cranes and Derricks in Construction (29 CFR Part 1926, Subpart CC and Subpart DD)*.[10]

This proposed rule requires no additional collection of information. OMB's approval of OSHA's ICR under Control Number 1218–0261 already covers all collections of information required by this proposed rule, and OSHA does not believe it is necessary to submit a new ICR to OMB seeking to collect additional information under this proposed rule.

Interested parties who comment on OSHA's determination that this proposal contains no additional paperwork requirements must send their written comments to the Office of Management and Budget, Attn: OMB Desk Officer for OSHA, Room 10235, 726 Jackson Place NW., Washington, DC 20503. OSHA also encourages commenters to submit their comments on this paperwork determination to it, along with their other comments on the proposed rule.

OSHA notes that a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), and the agency displays a currently valid OMB control number. The public need not respond to a collection of information requirement unless the agency displays a currently valid OMB control number, and, notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information requirement if the requirement does not display a currently valid OMB control number.

C. Federalism

OSHA reviewed this proposed rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions that would restrict state policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Executive Order 13132 provides for preemption of state law only with the expressed consent of Congress. Federal agencies must limit any such preemption to the extent possible.

Under Section 18 of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et seq.*), Congress expressly provides that states and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such states and territories as "State Plan States." Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. 29 U.S.C. 667. Subject to these requirements, State Plan States are free to develop and enforce under state law their own requirements for safety and health standards.

OSHA previously concluded from its analysis that promulgation of subpart CC complies with Executive Order 13132 (75 FR 48128–29). In states without an OSHA-approved State Plan, any standard developed from this proposed rule would limit state policy options in the same manner as every standard promulgated by OSHA. For State Plan States, Section 18 of the OSH Act, as noted in the previous paragraph,

[9] The ICR is available at ID–0425 at *www.regulations.gov* and at *www.reginfo.gov* (OMB Control Number 1218–0261).

[10] The request and OMB approval for discontinuing the previous Cranes and Derricks in Construction ICR (OMB Control Number 1218–0113) and the retitling of the ICR are available at *www.reginfo.gov*.

permits State-Plan States to develop and enforce their own cranes standards provided these requirements are at least as effective in providing safe and healthful employment and places of employment as the requirements specified in this proposal.

D. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, State Plan States must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, e.g., because an existing state standard covering this area is "at least as effective" as the new Federal standard or amendment (29 CFR 1953.5(a)). The state standard must be at least as effective as the final Federal rule. State Plan States must adopt the Federal standard or complete their own standard within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States do not have to amend their standards, although OSHA may encourage them to do so. The 21 states and 1 U.S. territory with OSHA-approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, Illinois, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to state and local government employees only.

When OSHA promulgates a new final rule, states and territories with approved State Plans must adopt comparable amendments to their standards for cranes and derricks within six months of OSHA's promulgation of the final rule unless they demonstrate that such a change is not necessary because their existing standards are already the same, or at least as effective, as OSHA's new final rule.

The proposed amendments to OSHA's cranes standard preserve the status quo and would not impose any new requirements on employers. Accordingly, State Plan States would not have to amend their standards to delay the effective date of their operator certification requirements, but they may do so if they so choose. However, if they choose to delay the effective date of their certification requirements, they also would need to include a corresponding extension of the employer duty to assess and train operators that is equivalent to § 1427(k)(2).

E. Unfunded Mandates Reform Act

When OSHA issued the final rule for cranes and derricks in construction, it reviewed the rule according to the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) and Executive Order 13132 (64 FR 43255 (Aug. 10, 1999). OSHA concluded that the final rule did not meet the definition of a "Federal intergovernmental mandate" under the UMRA because OSHA standards do not apply to state or local governments except in states that voluntarily adopt State Plans. OSHA further noted that the rule imposed costs of over $100 million per year on the private sector and, therefore, required review under the UMRA for those costs, but that its final economic analysis met that requirement.

As discussed above in Section IV.A (Preliminary Economic Analysis and Regulatory Flexibility Analysis) of this preamble, this proposed rule does not impose any costs on private-sector employers beyond those costs already taken into account in the final rule for cranes and derricks in construction. Because OSHA reviewed the total costs of this final rule under the UMRA, no further review of those costs is necessary. Therefore, for the purposes of the UMRA, OSHA certifies that this proposed rule does not mandate that state, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

F. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this proposed rule in accordance with Executive Order 13175 (65 FR 67249) and determined that it does not have "tribal implications" as defined in that order. As proposed, the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

G. Consultation With the Advisory Committee on Construction Safety and Health

Under 29 CFR parts 1911 and 1912, OSHA must consult with the Advisory Committee on Construction Safety and Health (ACCSH or Committee), established pursuant to Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*), in setting standards for construction work. Specifically, § 1911.10(a) requires the Assistant Secretary to provide the ACCSH with a draft proposed rule (along with pertinent factual information) and give the Committee an opportunity to submit recommendations. *See* also § 1912.3(a) ("[W]henever occupational safety or health standards for construction activities are proposed, the Assistant Secretary [for Occupational Safety and Health] shall consult the Advisory Committee"). Accordingly, the ACCSH met on May 23, 2013, and discussed OSHA's proposal to delay the crane operator certification deadline and extend the existing employer duties to assess and train crane operators pursuant to § 1926.1427(k).

During the ACCSH deliberations, one member of the ACCSH recommended extending the compliance date for qualification/certification indefinitely until OSHA completed a rulemaking on crane operator qualification. This member noted that extending the compliance date by three years would lead to new uncertainty, and not provide sufficient time for OSHA to complete a rulemaking that would clarify the responsibility of both crane operators and their employers (OSHA 2013–0006–0024, 133–134). Other members of the ACCSH agreed that it would be better to extend the compliance date indefinitely, allow OSHA to address the issue of crane operator qualification, and then establish a new compliance date for the industry once new guidance is in place (OSHA–2013–0006–0024, 136–137).

The ACCSH passed a motion recommending that OSHA suspend the operator certification requirement until OSHA completes a rulemaking on crane operator qualification, and require employers to continue to comply with the existing "phase-in" employer duties in § 1926.1427 during the same period (OSHA–2013–0006–0025, 30–31). (See OSHA's discussion of the ACCSH's motion under section I.D (Explanation of Proposed Action and Request for Comment) of this preamble.)

H. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) is "to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b), 655(b). A

safety or health standard is a standard "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment." 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. See *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980). In the cranes rulemaking, OSHA made such a determination with respect to the use of cranes and derricks in construction (75 FR 47913, 47920–21). This proposed rule does not impose any new requirements on employers. Therefore, this proposal does not require an additional significant risk finding (see *Edison Electric Institute* v. *OSHA,* 849 F.2d 611, 620 (D.C. Cir. 1988)).

In addition to materially reducing a significant risk, a safety standard must be technologically feasible. See *UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C. Cir. 1994). A standard is technologically feasible when the protective measures it requires already exist, when available technology can bring the protective measures into existence, or when that technology is reasonably likely to develop (see *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981); *American Iron and Steel Institute* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991)). In the 2010 Final Economic Analysis for the cranes standard, OSHA found the standard to be technologically feasible (75 FR 48079). This proposed rule would, therefore, be technologically feasible as well because it would not require employers to implement any additional protective measures; it would simply extend the duration of existing requirements.

List of Subjects in 29 CFR Part 1926

Construction industry, Cranes, Derricks, Occupational safety and health, Safety.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210, authorized the preparation of this notice. OSHA is issuing this proposed rule under the following authorities: 29 U.S.C. 653, 655, 657; 40 U.S.C. 3701 *et seq.;* 5 U.S.C. 553; Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012); and 29 CFR part 1911.

Signed at Washington, DC, on February 3, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons stated in the preamble of this proposed rule, OSHA proposes to amend 29 CFR part 1926 as follows:

PART 1926—[AMENDED]

Subpart CC—Cranes and Derricks in Construction

■ 1. The authority citation for subpart CC of 29 CFR part 1926 continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; and Secretary of Labor's Orders 5–2007 (72 FR 31159) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 2. In § 1926.1427, revise paragraph (k) to read as follows:

§ 1926,1427 Operator qualification and certification.

* * * * *

(k) *Phase-in.* (1) The provisions of this section became applicable on November 8, 2010, except for paragraphs (a)(2) and (f) of this section, which are applicable November 10, 2017.

(2) When paragraph (a)(1) of this section is not applicable, all of the requirements in paragraphs (k)(2)(i) and (ii) of this section apply until November 10, 2017.

(i) The employer must ensure that operators of equipment covered by this standard are competent to operate the equipment safely.

(ii) When an employee assigned to operate machinery does not have the required knowledge or ability to operate the equipment safely, the employer must train that employee prior to operating the equipment. The employer must ensure that each operator is evaluated to confirm that he/she understands the information provided in the training.

[FR Doc. 2014–02579 Filed 2–7–14; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2013–0399; FRL–9903–43]

RIN 2070–AB27

Proposed Significant New Use Rule on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for three chemical substances which were the subject of premanufacture notices (PMNs). This action would require persons who intend to manufacture (including import) or process any of the chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs.

DATES: Comments must be received on or before April 11, 2014.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2013–0399, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave. NW., Washington, DC. ATTN: Docket ID Number EPA–HQ–OPPT–2013–0399. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2013–0399. EPA's policy is that all comments received will be included in the docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business

Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR, are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for three chemical substances which were the subject of PMNs P–12–539, P–13–107, and P–13–109. These SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

In the **Federal Register** of August 7, 2013 (78 FR 48051) (FRL–9393–4), EPA issued direct final SNURs on these three chemical substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received notices of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), EPA removed the direct final SNURs in a separate final rule published in the **Federal Register** of November 5, 2013 (78 FR 66279) (FRL–9902–16), and is now issuing this

proposed rule on the three chemical substances. The record for the direct final SNURs on these chemical substances was established as docket EPA–HQ–OPPT–2013–0399. That record includes information considered by the Agency in developing the direct final rule.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the three chemical substances that are the subject of this proposed rule, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for three chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name.
- Chemical Abstracts Service (CAS) Registry number (assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this proposed rule, may be claimed as CBI.

This proposed rule includes PMN substances P–12–539, P–13–107, and P–13–109 that are subject to a "risk-based" and "exposure-based" consent order under TSCA section 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment, that the PMN substances are expected to be produced in substantial quantities, and that there may either be significant or substantial human exposure and/or the PMN substance may enter the environment in substantial quantities. This consent order requires protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "TSCA section 5(e) SNURs" on these PMN substances are proposed pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent order. The TSCA section 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent order.

PMN Numbers P–12–539, P–13–107, and P–13–109

Chemical names: Alkanes, C21–34-branched and linear, chloro (P–12–539), alkanes, C22–30-branched and linear, chloro (P–13–107), and alkanes, C24–28, chloro (P–13–109).

CAS numbers: 1417900–96–9 (P–12–539), 1401947–24–0 (P–13–107), and 1402738–52–6 (P–13–109).

Effective date of TSCA section 5(e) consent order: March 19, 2013.

Basis for TSCA section 5(e) consent order: The PMNs state that the uses of the PMN substances are as flame retardants/plasticizers in polymers and extreme pressure lubricants in metal working fluids (MWFs). There are also several CBI uses that are generically described as: Plasticizer and lubricant with flame retardant properties. By analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins (LCCPs—alkyl chain length of 18 to 20). The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these PMN substances may present an unreasonable risk of injury to the environment and the PMN substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the

PMN substances. To protect against these risks, the consent order requires:

1. Manufacture (including import) of the PMN substances at a cumulative, aggregate volume not to exceed 1,200,000 kilograms (kg), 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg unless the company has submitted the results of certain environmental effects studies.

2. No manufacture of the PMN substances with the amount of chlorinated paraffins, with an alkyl chain less than or equal to 20, to exceed more than 1% of that PMN substance by weight.

3. Risk notification.

Recommended testing: EPA has determined that analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry (GC/MS HPLC/MS)); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.3210), a modified SCAS test for insoluble and volatile chemicals (OPPTS Test Guideline 835.5045) or Zahn Wellens/EMPA test (OPPTS Test Guideline 835.3200); an aerobic and anaerobic transformation in soil test (Organisation for Economic Co-operation and Development (OECD) Test Guideline 307); a bioaccumulation in sediment-dwelling benthic oligochaetes (OECD Test Guideline 315) on the PMN substances and their potential degradation products; and sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD Test Guideline 233) or a sediment-water lumbriculus toxicity test using spiked sediment (OECD Test Guideline 225) on the PMN substances and their presumed degradation products would help characterize the effects of the PMN substances. Testing specifications are stated in the TSCA section 5(e) consent order for P–12–539, P–13–107, and P–13–109 which is available in the docket under docket ID number EPA–HQ–OPPT–2013–0399.

CFR citations: 40 CFR 721.10673 (P–12–539), 40 CFR 721.10674 (P–13–107), and 40 CFR 721.10675 (P–13–109).

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the three chemical substances that are subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health and environmental effects of the chemical substances. The basis for these findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent order.

B. Objectives

EPA is proposing these SNURs for specific chemical substances that have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at *http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.*

VI. Applicability of the Proposed Rule to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. A TSCA section 5(e) consent order has been issued for these chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent order from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) consent orders have been issued for these chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent order from undertaking activities which would be designated as significant new uses. The identities of the chemical substances subject to this proposed rule have not been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per 40 CFR 720.25 and § 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates February 10, 2014 as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) for a more detailed discussion of the cutoff date for ongoing uses.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance

has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines." The OECD test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.*

In the TSCA section 5(e) consent order for three of the chemical substances in this proposed rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study before reaching the specified production limit. The SNURs contain the same production volume limits as the TSCA section 5(e) consent order. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture (including import) or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances during the development of the direct final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2013–0399.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for three chemical substances that were the subject of PMNs and a TSCA section 5(e) consent order. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than $8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit IX., and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than $8,300.

Therefore, the promulgation of these SNURs would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), would not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 2, 2014.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add § 721.10673 to subpart E to read as follows:

§ 721.10673 Alkanes, C21-34-branched and linear, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C21–34-branched and linear, chloro (PMN P–12–539; CAS No. 1417900–96–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain ≤20) and § 721.80(p) (1,200,000 kilograms (kg), 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg of the aggregate of the PMN substances P–12–539 and P–13–109).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 3. Add § 721.10674 to subpart E to read as follows:

§ 721.10674 Alkanes, C22-30-branched and linear, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C22-30-branched and linear, chloro (PMN P–13–107; CAS No. 1401947–24–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain ≤ 20) and § 721.80(p) (14,100,000 kilograms (kg), 59,100,000 kg, 78,400,000 kg, 86,100,000 kg of PMN substance P-13-107, from March 19, 2013).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 4. Add § 721.10675 to subpart E to read as follows:

§ 721.10675 Alkanes, C24-28, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C24-28, chloro (PMN P-13-109; CAS No. 1402738–52–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain ≤ 20) and § 721.80(p) (1,200,000 kilograms (kg), 14,100,000 kg, 78,400,000 kg, 86,100,000 kg of the aggregate of the PMN substances P-12-539 and P-13-109).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2014–02846 Filed 2–7–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Chapter X

[Docket No. EP 711]

Petition for Rulemaking to Adopt Revised Competitive Switching Rules

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of rescheduled public hearing.

SUMMARY: The Surface Transportation Board (the Board) will hold a public hearing to explore further the issues surrounding the petition by The National Industrial Transportation League (NITL) and the related comments filed in this proceeding.

DATES: The hearing will be held on March 25 and 26, 2014, beginning at 9:30 a.m., in the Hearing Room at the Board's headquarters located at 395 E Street SW., Washington, DC. The hearing will be open for public observation.

FOR FURTHER INFORMATION CONTACT: Valerie Quinn at (202) 245–0382. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: By decision served on July 25, 2012, the Board began a proceeding to consider a proposal submitted by NITL to modify the Board's standards for mandatory competitive switching. Under the proposal, certain captive shippers located in terminal areas would be granted access to a competing railroad if there is a working interchange within a reasonable distance (30 miles under NITL's proposal). In its decision, the Board sought empirical information about the impact of the proposal if it were to be adopted. The Board received numerous comments in response to its decision. In order to explore further NITL's proposal and the issues raised in the submitted comments, the Board scheduled a public hearing for October 22, 2013. The Board received numerous notices of intent to participate in that hearing. By decision served on October 16, 2013, the Board postponed the hearing due to the Government shutdown. The Board is now rescheduling the hearing for March 25 and 26, 2014.

Additional information—including the schedule of appearances and time allotments—is contained in the Board's decision, which is available on our Web site, *http://www.stb.dot.gov.* Copies of the decision may be purchased by contacting the Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238. Assistance for the hearing impaired is available through FIRS at (800) 877–8339.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

A public hearing in this proceeding will be held on March 25 and 26, 2014, at 9:30 a.m., in the Board's Hearing Room, at 395 E Street SW., Washington, DC, as described above.

Decided: February 3, 2014.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2014–02941 Filed 2–7–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2013–0073; FXES11130900000C2–134–FF09E32000]

RIN 1018–AY00

Endangered and Threatened Wildlife and Plants; Removing the Gray Wolf (Canis lupus) From the List of Endangered and Threatened Wildlife and Maintaining Protections for the Mexican Wolf (Canis lupus baileyi) by Listing It as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability and reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our June 13, 2013, proposal to remove the gray wolf (*Canis lupus*) from the List of Endangered and Threatened Wildlife but to maintain endangered status for the Mexican wolf by listing it as a subspecies (*Canis lupus baileyi*). We also announce the availability of the independent scientific peer review report on the proposal. We are reopening the comment period for 45 days to allow all interested parties an opportunity to comment on our proposed rule in light of the peer review report on this proposal. The comment period is scheduled to close on March 27, 2014. Comments previously submitted need not be resubmitted and will be fully considered in preparation of the final rule.

DATES: The public comment period on the proposal to remove the gray wolf (*Canis lupus*) from the List of Endangered and Threatened Wildlife but to maintain endangered status for the Mexican wolf by listing it as a subspecies (*Canis lupus baileyi*) that was published on June 13, 2013 (78 FR 35664), is reopened and will close on March 27, 2014. Please note comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. If you are submitting your comments by hard copy, please mail them by March 27, 2014, to ensure that we receive them in time to give them full consideration.

ADDRESSES: *Document availability:* The June 13, 2013, proposal (78 FR 35664) is available online at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2013–0073 and at *http://www.gpo.gov/fdsys/pkg/FR-2013-06-13/pdf/2013-13982.pdf.* The independent scientific peer review report on the proposal is available online at *http://www.fws.gov/home/wolfrecovery* and at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2013–0073.

Written Comments: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* Search for Docket No. FWS–HQ–ES–2013–0073. Please ensure you have found the correct document before submitting your comments. If your comments will fit in the provided comment box, please use this feature of *http://www.regulations.gov,* as it is most compatible with our comment review procedures. If you attach your

comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–ES–2013–0073; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will post all comments we receive on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Headquarters Office, Ecological Services; telephone (703) 358–2171; facsimile (703) 358–1735. Direct all questions or requests for additional information to: GRAY WOLF QUESTIONS, U.S. Fish and Wildlife Service, Headquarters Office, Ecological Services, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203. Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Service evaluated the classification status of gray wolves (*Canis lupus*) currently listed in the contiguous United States and Mexico under the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*). Based on our evaluation, we published a proposed rule on June 13, 2013 (78 FR 35664), to remove the gray wolf from the List of Threatened and Endangered Wildlife but to maintain endangered status for the Mexican wolf by listing it as a subspecies (*C. l. baileyi*). We proposed these actions because we determined that the best available scientific and commercial information indicates that the currently listed entity is not a valid species under the ESA and that the Mexican wolf (*C. l. baileyi*) warrants listing as an endangered subspecies.

Upon publication of the proposed rule (June 13, 2013, 78 FR 35664), the Service opened the public comment period on the proposal. On September 5 and October 2, 2013, we announced public hearings on the proposed rule (78 FR 54614 and 78 FR 60813). The September 5 notice also extended the public comment period for the proposed rule to October 28, 2013. Following delays caused by the Federal Government lapse in appropriations, the Service announced rescheduled dates for three of the public hearings, scheduled a fifth public hearing, and extended the public comment period for the proposed rule to December 17, 2013 (78 FR 64192, October 28, 2013). The Service is now reopening the public comment period on the proposal in conjunction with the submission of the peer review report.

In accordance with the Service's July 1, 1994 peer review policy (59 FR 34270) and the Office of Management and Budget's December 16, 2004, Final Information Quality Bulletin for Peer Review, the Service subjected this proposal to independent expert peer review. The purpose of seeking independent peer review is to ensure use of the best scientific and commercial information available and to ensure and maximize the quality, objectivity, utility, and integrity of the information upon which the proposal is based, as well as to ensure that reviews by qualified experts are incorporated into the rulemaking process. The National Center for Ecological Analysis and Synthesis (NCEAS), a research center located at the University of California, Santa Barbara, sponsored this peer review. Additional information on the nature of the peer review can be found in the statement of work at: *http://www.fws.gov/science/pdf/Gray_Wolf_Proposed_Delisting_SOW_Peer_Review_12-13-2013_Final.pdf*.

Public Comments

We will accept written comments and information during the reopened comment period on our proposal to remove the gray wolf (*Canis lupus*) from the List of Endangered and Threatened Wildlife but to maintain endangered status for the Mexican wolf by listing it as a subspecies (*Canis lupus baileyi*). This proposal published in the **Federal Register** on June 13, 2013 (78 FR 35664).

For the types of information for which we are seeking public comments, please see the Public Comments section of the June 13, 2013, proposed rule (78 FR 35664).

Please note that submissions merely stating support for or opposition to the actions under consideration without providing supporting information, although noted, will not be considered in making a determination. You may submit your comments and materials by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov*. If you provide personal identifying information, such as your street address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as some of the supporting documentation we used in preparing the proposed rule, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–HQ–ES–2013–0073, or by appointment, during normal business hours at the office location listed under **FOR FURTHER INFORMATION CONTACT.**

We intend that any final action resulting from the proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, tribes, the scientific community, industry, or other interested parties concerning the proposed rule. We request that you make your comments as specific as possible and explain the basis for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you reference or provide.

Our final determination concerning the proposed action will take into consideration all written comments we receive during all comment periods, comments from peer reviewers, and comments received during the public hearings. The comments will be included in the public record for the rulemaking, and we will fully consider them in the preparation of our final determination.

If you previously submitted comments or information on the proposed rule, please do not resubmit them. We will incorporate them into the corresponding public record as part of this comment period, and will fully consider them in the preparation of our final determination.

Authors

The primary authors of this notice are the Ecological Services staff of the Headquarters Office, U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: January 31, 2014.

Daniel M. Ashe,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2014–02817 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 79, No. 27
Monday, February 10, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 4, 2014.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program: State Issuance and Participation Estimates—Forms FNS-388 and FNS–388A.

OMB Control Number: 0584–0081.

Summary of Collection: Section 18(b) of Food and Nutrition Act, (the Act) 7 U.S.C. 2027(b), limits the value of allotments paid to SNAP households to an amount not in excess of the appropriation for the fiscal year. Timely State monthly issuance estimates are necessary for the Food and Nutrition Service (FNS) to ensure that it remains within the appropriation and will have a direct effect upon the manner in which allotments would be reduced if necessary. While benefit reductions have never been ordered in the past under Section 18(b) nor are they anticipated based on current data, the Department must continue to monitor actual program costs against the appropriation.

Need and Use of the Information: FNS uses the FNS–388 report to obtain monthly estimated or actual issuance and participation data for the current and previous months. The FNS–388 is being updated to include separate reporting of Disaster SNAP benefit issuance and participation data which will improve data accountability and ensure data is available on a monthly basis for timely response to Federal, State and other inquiries. In addition, State agencies are required to submit a project area breakdown on the FNS–388, of issuance and participation data twice a year. The project area breakdown attached to the FNS–388, twice a year is known as the FNS–388A. This data is useful in identifying project areas that operate fraud detection units in accordance with the Act.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Recordkeeping; Reporting: Monthly; semi-annually.

Total Burden Hours: 5,187.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–02769 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 4, 2014.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by March 12, 2014 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20503. Commentors are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Financial Information Security Request Form.

OMB Control Number: 0596–0204.

Summary of Collection: The majority of Forest Service's (FS) financial records are in databases stored at the National Finance Center (NFC). The Federal Information Security Reform Act of 2002 (Pub. L. 107–347) and Information Technology Management Reform Act of 1996 (Pub. L. 104–106) authorize the Forest Service to obtain information necessary for contracted employees to access and maintain these records.

Need and Use of the Information: The Forest Service uses a paper and electronic version of its form FS–6500–214 to gather name, work email, work telephone number, job title etc. for a specific contracted employee to apply to NFC for access. Prior to filling out the firm, contractors must first complete specific training before a user may request access to certain financial systems. NFC grants access to users only at the request of Client Security Officers. The unit's Client Security Officer is responsible for management of access to computers and coordinates all requests for NFC. The information collected is shared with those managing or overseeing the financial systems used by the FS, this includes auditors.

Description of Respondents: Contracted employees.

Number of Respondents: 415.

Frequency of Reponses: Reporting: Yearly.

Total Burden Hours: 1,132.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–02770 Filed 2–7–14; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0103]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Johne's Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the interstate movement of animals affected with Johne's disease.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0103-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0103, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0103* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the interstate movement of animals affected with Johne's disease, contact Dr. Dean Goeldner, Senior Staff Veterinarian, Cattle Health Center, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737; (301) 851–3511. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: Johne's Disease.

OMB Control Number: 0579–0338.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) is authorized, among other things, to prevent the introduction and interstate spread of serious diseases and pests of livestock and for eradicating such diseases and pests from the United States when feasible. In support of this mission, APHIS' Veterinary Services (VS) prohibits or restricts the interstate movement of livestock that have, or have been exposed to, certain diseases.

Johne's disease, also known as paratuberculosis, is caused by *Mycobacterium avium* subspecies paratuberculosis and primarily affects cattle, sheep, goats, and other domestic, exotic, and wild ruminants. The disease is a chronic and contagious enteritis that results in progressive wasting and eventual death. It is nearly always introduced into a healthy herd by an infected animal that is not showing symptoms of the disease.

The regulations in 9 CFR, chapter I, subchapter C, govern the interstate movement of animals to prevent the dissemination of livestock and poultry diseases in the United States. Subchapter C, part 71, contains general provisions for the interstate movement of animals, poultry, and their products, while part 80 pertains specifically to the interstate movement of domestic animals that are positive to an official test for Johne's disease. These regulations provide that cattle, sheep, goats, and other domestic animals that are positive to an official test for Johne's disease may generally be moved interstate only to a recognized slaughtering establishment or to an approved livestock facility for sale to such an establishment. They may also be moved for purposes other than slaughter under certain conditions.

APHIS previously supplemented these regulations with standards outlined in the document, "Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program" (VBJDCP). However, in 2012, APHIS discontinued the VBJDCP and States began conducting their own Johne's disease monitoring programs and using their own forms rather than those required by APHIS and previously approved by the Office of Management and Budget (OMB) under OMB control number 0579–0338. As a result, APHIS has revised the information collection activities for the Johne's disease program to only require a USDA–APHIS VS Permit for Movement of Restricted Animals (VS Form 1–27) and official ear tags.

Due to the reduction in the number of forms required by APHIS, the estimated annual number of respondents has decreased from 9,125 to 3, the estimated annual number of responses has decreased from 66,105 to 6, and the estimated total annual burden on respondents has decreased from 38,187 hours to 3 hours.

We are asking OMB to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the

Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.5 hours per response.

Respondents: Accredited veterinarians, herd owners, and livestock shippers.

Estimated annual number of respondents: 3.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 6.

Estimated total annual burden on respondents: 3 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02761 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0099]

Notice of Request for Approval of an Information Collection; National Animal Health Laboratory Network Qualification Checklist for Membership

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with the National Animal Health Laboratory Network qualification checklist for membership.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0099-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0099, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0099* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the National Animal Health Laboratory Network qualification checklist, contact Mrs. Kelly Burkhart, Microbiologist, National Animal Health Laboratory Network, NVSL, VS, APHIS, 1920 Dayton Road, Ames, IA 50010; (515) 337–7731. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Laboratory Network Qualification Checklist for Membership.

OMB Control Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: The National Animal Health Laboratory Network (NAHLN) is a cooperative effort between two agencies within the U.S. Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) and the National Institute of Food and Agriculture (NIFA). NAHLN was established to coordinate the testing capacities of Federal veterinary diagnostic laboratories with the extensive infrastructure of State and university veterinary diagnostic laboratories. This network enhances the United States' early detection of and response to animal health emergencies, including bioterrorists events, newly emerging disease, and foreign animal disease agents that could threaten the nation's food supply and public health.

In 2002, NAHLN was created when APHIS and NIFA entered into cooperative agreements with 12 State and university veterinary diagnostic laboratories. APHIS has since contracted with additional State and university diagnostic laboratories to assist with testing and surveillance, and NAHLN currently consists of 56 State and university laboratories as well as other Federal laboratories.

At the Federal level, APHIS' National Veterinary Services Laboratories (NVSL) serves as the national veterinary diagnostic reference and confirmatory laboratory. NVSL coordinates activities, participates in methods validation, and provides training, proficiency testing, assistance, materials, and prototypes for diagnostic testing. NVSL also reviews the qualifications of non-USDA laboratories for approval to participate in NAHLN surveillance activities.

As part of the approval process, APHIS requires the use of certain information collection activities, including instructions, policy documentation, quality document verification, documentation of accreditation, documentation of implemented quality system, and approval certificates and cover letters.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 8.483 hours per response.

Respondents: Laboratory directors and State animal health officials.

Estimated annual number of respondents: 60.

Estimated annual number of responses per respondent: 6.

Estimated annual number of responses: 360.

Estimated total annual burden on respondents: 3,054 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02759 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0104]

Notice of Request for Approval of an Information Collection; National Animal Health Laboratory Network Laboratories Annual Inventory Verification for USDA-Owned Equipment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with the National Animal Health Laboratory Network laboratories annual inventory verification for U.S. Department of Agriculture-owned equipment.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0104-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0104, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0104* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the National Animal Health Laboratory Network laboratories annual inventory verification, contact Ms. Cindy Chard-Bergstrom, Microbiologist, National Animal Health Laboratory Network, NVSL, VS, APHIS, 1920 Dayton Road, Building 20, Ames, IA 50010; (515) 337–7198. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Laboratory Network Laboratories Annual Inventory Verification for USDA-Owned Equipment.

OMB Control Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: The National Animal Health Laboratory Network (NAHLN) is a cooperative effort between two agencies within the U.S. Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) and the National Institute of Food and Agriculture (NIFA). NAHLN was established to coordinate the testing capacities of Federal veterinary diagnostic laboratories with the extensive infrastructure of State and university veterinary diagnostic laboratories. This network enhances the United States' early detection of and response to animal health emergencies, including bioterrorists events, newly emerging disease, and foreign animal disease agents that could threaten the nation's food supply and public health.

In 2002, NAHLN was created when APHIS and NIFA entered into cooperative agreements with 12 State and university veterinary diagnostic laboratories. APHIS has since contracted with additional State and university diagnostic laboratories to assist with testing and surveillance, and NAHLN currently consists of 56 State and university laboratories as well as other Federal laboratories.

At the Federal level, APHIS' National Veterinary Services Laboratories (NVSL) serves as the national veterinary diagnostic reference and confirmatory laboratory. NVSL coordinates activities, participates in methods validation, and provides training, proficiency testing, assistance, materials, and prototypes for diagnostic testing. NVSL also reviews the equipment used by the laboratories within the NAHLN to ensure that the non-USDA laboratories have the equipment resources needed to perform any necessary testing.

As part of the review process, APHIS requires the use of certain information collection activities, including a review spreadsheet, verification of equipment information, the addition of information to the list, and submission of completed spreadsheets.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.5705 hours per response.

Respondents: Laboratory directors and State animal health officials.

Estimated annual number of respondents: 39.

Estimated annual number of responses per respondent: 4.

Estimated annual number of responses: 156.

Estimated total annual burden on respondents: 89 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02762 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0088]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Blood and Tissue Collection at Slaughtering and Rendering Establishments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for blood and tissue collection at slaughtering and rendering establishments to enhance animal disease surveillance.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0088-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0088, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0088* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for blood and tissue collection at slaughtering and rendering establishments, contact Dr. Debra Cox, Senior Staff Veterinarian, Cattle Health Center, SPRS, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737; (301) 851–3504. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: Blood and Tissue Collection at Slaughtering and Rendering Establishments.

OMB Control Number: 0579–0212.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is authorized, among other things, to prevent the interstate spread of livestock diseases and for eradicating such diseases from the United States when feasible. As part of this mission, APHIS' Veterinary Services (VS) conducts animal disease surveillance programs, including diagnostic testing.

The regulations in 9 CFR, subchapter C, part 71, "General Provisions," provide for the collection of blood and tissue samples from livestock (horses, cattle, bison, captive cervids, sheep and goats, swine, and other farmed animals) and poultry at slaughter. Persons moving livestock and poultry interstate for slaughter may only move the animals to slaughtering or rendering establishments that have been listed by the Administrator of APHIS. At APHIS' discretion, slaughtering or rendering establishment personnel will collect blood and tissue samples to assess the prevalence of disease and to identify sources of disease.

Section 71.21 contains the requirements for tissue and blood testing at slaughter and requires the completion of certain information collection activities. Federal personnel, in conjunction with establishment personnel, are required to complete a listing agreement and a USDA-APHIS VS "USDA Listed Slaughter Facility Inspection Report" (VS Form 10–5). If the Administrator denies or withdraws an establishment's listing, the establishment may appeal the denial or withdrawal in writing to the Administrator. In addition, if an operator of a facility notifies the Administrator, in writing, that the facility will no longer handle livestock moved interstate in accordance with the regulations, the Administrator will withdraw an establishment's listing.

The above information collection activities and the USDA-APHIS National Veterinary Services Laboratories Specimen Submission Form/Continuation Sheet (VS Form 10–4/10–4A) for collection of bovine spongiform encephalopathy (BSE) specimens were previously approved by the Office of Management and Budget (OMB) under this collection. However, APHIS will no longer require VS Form 10–4/10–4A and will be instituting the use of an electronic form for use with BSE specimens under 0579–0409, which is a recently approved information collection.

Though APHIS will no longer require VS Form 10–4/10–4A, we estimate that there will be an increase in the number of respondents for this collection based on a final rule published in the **Federal Register** on May 7, 2013 [1] (78 FR 26486–26489, APHIS–2007–0039). APHIS anticipates being able to collect listing agreements and facility inspection reports from nearly all U.S. slaughtering and rendering establishments. As a result, we have increased the estimated number of respondents from 66 to 1,925. However, based on the removal of the VS Form 10–4/10–4A, the estimated annual number of responses and the estimated total annual burden on respondents have decreased from 10,747 to 9,628 and 2,691 hours to 1,605 hours, respectively.

We are asking OMB to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

[1] To view the final rule, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0039.*

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.1667 hours per response.

Respondents: Accredited veterinarians and slaughter and rendering establishment personnel.

Estimated annual number of respondents: 1,925.

Estimated annual number of responses per respondent: 5.

Estimated annual number of responses: 9,628.

Estimated total annual burden on respondents: 1,605 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02757 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0101]

Notice of Request for Approval of an Information Collection; National Veterinary Services Laboratories Request Forms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection concerning the National Veterinary Services Laboratories request forms.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0101-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0101, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0101* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the National Veterinary Services Laboratories request forms, contact Dr. Nancy Clough, Veterinary Medical Officer, STAS, NVSL, VS, APHIS, 1920 Dayton Road, Ames, IA 50010; (515) 337–7989. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: National Veterinary Services Laboratories Request Forms.

OMB Control Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is authorized, among other things, to carry out activities to detect, control, and eradicate pests and diseases of livestock within the United States. To carry out this mission, APHIS' National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system.

Upon request, NVSL's support activities provide reagents or supplies and training to domestic and foreign diagnostic laboratories, governments, researchers, and private veterinary practitioners. This support service involves information collection activities, including a USDA, APHIS, NVSL Request for Reagents or Supplies Form (Veterinary Services (VS) Form 4–9); an NVSL Contact Information Update Form (VS Form 4–10); and a USDA, APHIS, VS, NVSL Application for Laboratory Training (VS Form 4–11).

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.2489 hours per response.

Respondents: Domestic and foreign diagnostic laboratories (Federal, State, university, or private), researchers (academia, private, government), and private veterinary practitioners.

Estimated annual number of respondents: 1,085.

Estimated annual number of responses per respondent: 3.488.

Estimated annual number of responses: 3,785.

Estimated total annual burden on respondents: 942 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02760 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2009–0101]

Response to Petitions for the Reclassification of Light Brown Apple Moth as a Non-Quarantine Pest

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are notifying the public of our decision to maintain our classification of the light brown apple moth (LBAM, *Epiphyas postvittana* [Walker]) as a quarantine pest. In making this decision, the Animal and Plant Health Inspection Service (APHIS) evaluated the possibility of and impact from reclassifying LBAM from an actionable, quarantine-significant pest to a non-actionable, non-quarantine pest. By maintaining a regulatory program for LBAM, APHIS is seeking to minimize the further spread of the moth in the United States and maintain foreign trade markets for our producers. This decision is based on our evaluation of data submitted by the two petitioners seeking the reclassification of LBAM, our analysis of other scientific data, and comments received from the public in response to our previous notice announcing the availability of our revised draft response to those petitions.

DATES: *Effective Date:* February 10, 2014.

ADDRESSES: You may read the documents referenced in this notice and the comments we received in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming. Those documents are also available on the Internet on the Regulations.gov Web site at *http://www.regulations.gov/#!docketDetail;D=APHIS–2009–0101.*

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Simao, National Policy Manager, Pest Management, PPQ—Plant Health Programs, APHIS, 4700 River Road Unit 26, Riverdale, MD 20737–1231; (301) 851–2067.

SUPPLEMENTARY INFORMATION:

Background

Light brown apple moth (*Epiphyas postvittana* [Walker]) (LBAM) is a plant pest native to Australia with a broad host range of over 2,000 plant species, including stone fruit (peaches, plums, nectarines, cherries, and apricots), apples, pears, grapes, and citrus. LBAM larvae feed on the leaves and fruit of host plants and, under appropriate conditions, may result in significant damage. To date, natural enemies of leaf rollers have not impacted LBAM populations in the infested areas of California and few predators or parasites of LBAM have been observed.

LBAM was detected in the late 1800s in Hawaii. The interstate movement from Hawaii of cut flowers, fruits and vegetables, plants, and portions of plants, including LBAM host material, is currently prohibited unless the articles are first inspected and found free of plant pests (including LBAM) or are treated for plant pests.

Moths suspected of being LBAM were detected in Alameda and Contra Costa Counties, CA, in February 2007, and were subsequently confirmed as LBAM on March 16, 2007. Due to California's cooler climate and the potential impact of LBAM on a wide range of crops, a response program has been conducted by the State of California with support from the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture.

APHIS' current regulatory framework and response program for LBAM is outlined in a Federal Order, which was issued on June 13, 2012, to prevent the further spread of LBAM from infested to noninfested areas. The order established restrictions on the interstate movement of regulated articles from areas where LBAM infestations are known to exist. Federal Orders were also in place prior to June 13, 2012, to prevent the further spread of LBAM from infested to noninfested areas.

On September 12, 2008, and February 4, 2009, petitions were submitted to the Secretary of Agriculture requesting that APHIS reclassify LBAM from an actionable, quarantine-significant pest to a non-actionable, non-quarantine pest and that APHIS remove the Federal restrictions placed on the interstate movement of LBAM host articles from areas where the pest had been detected. The petitions also questioned APHIS' ability to eradicate LBAM, the appropriateness of technologies used to support the eradication program, the potential impacts of these technologies on the environment and on human health and safety, and the effectiveness of the communication strategies used to inform the public about the LBAM program.

APHIS requested that the National Academy of Sciences (NAS) conduct an independent review of our draft response to the petitions. Based on the NAS' findings and recommendations, APHIS revised its initial draft response to the petitions. On March 15, 2010, APHIS published a notice [1] in the **Federal Register** (75 FR 12172–12173, Docket No. APHIS–2009–0101) announcing the availability, for review and comment, of our revised draft response to the petitions. We solicited comments for 60 days through May 14, 2010, and received 114 comments by that date. Three commenters supported the continued regulation of LBAM as a quarantine pest. The remaining commenters expressed concerns regarding the continued regulation of LBAM as a quarantine pest. These concerns are discussed below by topic.

Reclassification

The majority of commenters requested that we reclassify LBAM as a non-quarantine pest.

LBAM meets the Plant Protection Act's (PPA) definition of a plant pest. The PPA defines the term "plant pest" as any living stage of protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the previous articles that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

In addition to concurring with APHIS' conclusion that LBAM meets the definition of a plant pest under the PPA, the NAS reviewers agreed that LBAM also met the definitions of quarantine pest as defined in the International Plant Protection Convention and of an alien species per Executive Order 13112, "Invasive Species." As NAS noted, APHIS demonstrated that LBAM is not native, is present within the United States in a limited distribution, and may cause economic harm.

Due to its extensive host range and potential to establish, LBAM continues to be a significant concern to foreign trading partners as well as to States not currently infested with LBAM and which are at risk of becoming infested. A key reason for classifying and continuing to classify LBAM as a reportable/actionable pest is the potential economic impact associated with the detection and spread of the pest to areas in the United States where it could become established or where it might be introduced seasonally. In

[1] To view the notice, draft response, and the comments we have received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS–2009–0101.*

calendar year 2007, the value of sales of potential LBAM hosts among the at-risk States totaled $69.4 billion, which represented 52 percent of the total value of all reported plant sales within at-risk States.

To date, APHIS has received two Special Need Requests under our regulations in

7 CFR part 301.1–2 from States seeking APHIS approval for State restrictions that are in addition to those imposed by the Federal program for nursery products from California to further ensure protection from the interstate movement of LBAM in commerce. Should APHIS reclassify LBAM as a nonactionable pest, other States have indicated that they would likely enact their own quarantines for LBAM that would restrict the movement of articles from California. Producers would then have to meet varying and perhaps stricter requirements for each State to which they ship their products, most likely resulting in increased costs for both production and LBAM control. Without sufficient regulations to demonstrate to trading partners that our efforts are successful in minimizing the impacts of LBAM within California, the ability of these industries to export internationally or domestically would be compromised.

One commenter asked that the quarantine for intrastate movement be lifted, stating that intrastate movement restrictions are burdening local market producers.

The intrastate movement of LBAM host articles is regulated by the California Department of Food and Agriculture (CDFA) not APHIS, so we cannot make the changes requested in this comment.

Several commenters expressed concern that the LBAM program remains focused on eradication as the goal.

In March 2010, APHIS announced through a press release as well as via calls with stakeholders that the objective of the LBAM program has changed from eradication to suppression and control of the moth's spread into noninfested areas of the United States.

Introduction Into the United States

Many commenters disagreed with APHIS' designation of LBAM as a newly introduced pest, stating that trapping surveys conducted prior to 2005 were inadequate to detect the presence of LBAM and that independent scientists believe that LBAM may have been in California for 10 to 30 years based upon the number of LBAM interceptions at the ports of entry. Several commenters stated that the idea of LBAM being recently introduced was inconsistent with invasive pest literature, which indicates that new plant pest invaders require a long adjustment period and that early stages of invasion are difficult to detect.

The lack of any LBAM findings in the data from a 2005 Cooperative Agricultural Pest Survey in the areas of California currently infested with LBAM show that it is unlikely that LBAM has been present in the United States for a decade or more. Additionally, trapping surveys conducted by growers in the San Francisco and Monterey Bay areas, CA, in 2006, did not detect the presence of LBAM prior to the initial detection in Alameda and Contra Costa Counties, CA, in 2007.

Although LBAM had previously been intercepted at ports of entry, this does not demonstrate that the moth had become established within the United States. No LBAM were detected beyond its known distribution in California in State-based surveys conducted nationwide in 2008 and 2009. In addition, since the publication of the petition response, the journal *American Entomologist* published an article entitled "Biology, Identification, and History of the Light Brown Apple Moth, *Epiphyas postvittana* (Walker) (Lepidoptera: Tortricidae: Archipini) in California," [2] that stated that surveillance over the past 40 years for LBAM specifically, as well as other Lepidoptera, failed to detect the moth.

One commenter stated that since LBAM has been established in the United States for many years, there is no reason to continue regulating it. Two commenters stated that the genetic diversity of the LBAM population present in California supports the idea that there have been multiple introductions of LBAM, thereby suggesting LBAM was likely present prior to detection in 2007.

While two independent analyses of mitochondrial DNA indicate that multiple introductions of LBAM in Northern California may have occurred, a single large invasion cannot be ruled out.[3] [4] The analyses do not confirm that LBAM was established prior to detection in 2007 since multiple, recent introductions occurring within a single year may have been possible.

Modeling

Several commenters expressed concern that the North Carolina State University APHIS Plant Pest Forecasting System (NAPPFAST) model inaccurately determined the potential for LBAM establishment and economic damage. One commenter stated that one of the flaws of the model was that it lacked LBAM detectability metrics and relied on qualitative statements rather than quantitative evidence. Several commenters expressed their concern that the science used to determine the APHIS response was inaccurate, including the climatic modeling used to predict crop losses and economic damages.

In response to these concerns, APHIS invited Dr. Andrew Gutierrez from the University of California, Berkeley, to meet and discuss potential predictive modeling approaches that may be useful to APHIS in better understanding pest spread and distribution. Dr. Gutierrez suggested that APHIS also use Climex and Demographic models to understand and predict LBAM spread and distribution. As discussed below, APHIS also used these other modeling approaches recommended by Dr. Gutierrez that explore the influence of ecological factors on pest populations rather than relying predominantly on temperature-based modeling.

The initial output from the NAPPFAST, Climex, and Demographic models estimated areas suitable for LBAM establishment. Most importantly, all three model outputs estimated that significant areas of the United States, particularly in the Southeast, were suitable for LBAM establishment. All models are in general agreement for areas estimated to be unsuitable for establishment based on cold temperatures. The Climex and Demographic models agreed that some areas in the Southwestern United States are unsuitable for LBAM establishment due to high temperatures. The NAPPFAST model, which does not currently incorporate high temperature mortality, disagrees and probably overestimated suitable areas in the Southwest.

[2] Brown, John W., Epstein, Marc E., Gilligan, Todd M., Passoa, Steven C., Powell, Jerry A., "Biology, Identification, and History of the Light Brown Apple Moth, Epiphyas *postvittana* (Walker) (Lepidoptera: Tortricidae: Archipini) in California," *Americon Entomologist*, vol. 56, No. 1, pp. 34–43 (Spring 2010).

[3] Rubinoff, D., B.S. Holland, M.S. Jose, and J.A. Powell. (2011) Geographic proximity not a prerequisite for invasion: Hawaii not the source of California invasion by light brown apple moth (*Epiphyos postvittana*). PLoS ONE, Vl 6 (1): e16361.

[4] Tooman, L., C.J. Rose, C. Carraher, D.M. Suckling, S. Rioux-Pasquette, L.A. Ledezma, T.M. Gilligan, M. Epstein, N.B. Barr, and R.D. Newcomb. (2011) Global mitochondrial population genetics of the invasive pest, *Epiphyos postvittono. Journol of Economic Entomology*, vol. 104, No. 5, pp. 1706–1719 (2011).

Trapping

Several commenters stated that the increase in LBAM trapping finds may be due to an increase in trapping efficiency rather than to an increase in LBAM populations. One commenter stated that the increase in LBAM trap finds is irrelevant because it does not indicate potential for damage.

The trapping equipment has not changed and protocols for delimiting a detection remained constant until October 2012. The increased trap finds indicate that LBAM is spreading into new areas, increasing the potential for damage. While trapped moths by themselves do not demonstrate damage, the potential harm caused by LBAM has been discussed above and is further discussed below.

Chemicals

The majority of commenters expressed concern regarding the impacts on the environment and human and animal health associated with the use of pesticides and chemicals to control LBAM. The commenters expressed concern that chemicals used for the control of LBAM had not been tested on humans and that formulations had not been disclosed. Many commenters stated that LBAM is present in other countries and that it is considered a minor pest which is easily and cost-effectively managed as a crop-quality issue.

Under the National Environmental Policy Act of 1969 (NEPA) as amended (42 U.S.C. 4321 *et seq.*), APHIS is required to analyze our proposed control actions to determine if they will have an adverse effect on the environment before implementing the actions. In 2008, APHIS completed a programmatic environmental assessment for LBAM (available at *http://www.aphis.usda.gov/plant_health/ea/downloads/lbam-treatmentprog-02-14-08.pdf*), which evaluated two approaches: No action and treatment alternative. The treatment alternative consisted of maintaining the then applicable Federal Quarantine Order to prevent the destructive spread of the LBAM infestation, as well as implementing an LBAM eradication program in California to stop the further spread of LBAM in California. Because damage caused by LBAM can significantly threaten agricultural production in the United States, APHIS determined that the treatment alternative was the best approach to mitigating these effects and that no significant impact on human health or the environment would result from the proposed LBAM eradication program. That Finding of No Significant Impact is available at *http://www.aphis.usda.gov/plant_health/ea/downloads/lbam-fonsi-pheremone.pdf.*

The United States Environmental Protection Agency (EPA) administers regulations for the protection of human health and the environment. In 2001, EPA approved the organic pheromone Checkmate for use in the United States, finding that it did not have adverse impacts on human health. This pheromone is used to suppress LBAM and has no known biological activity in other insect species. The pheromone simulates the female LBAM odor to attract and confuse the male LBAM, making it difficult for the males to find a female moth for mating. An analysis of the pheromone formulation indicated that if brought into contact with either the eye or skin it may cause slight irritation. However, this contact is unlikely to occur since the pheromone is distributed via a plastic tube dispenser that is secured to trellises, fences, and other fixtures.

One commenter stated that there is no evidence to suggest that using mating disruption via pheromones, either alone or in conjunction with other methods, is able to successfully eradicate an insect population.

The response program uses a multi-layered control and suppression strategy for LBAM that includes mating disruption, pesticide application, sterile insect technique, biological control, ongoing surveys, and regulatory controls on agricultural commodities moving out of the quarantined area. Mating disruption has been extensively studied and used successfully in Australia and New Zealand to minimize LBAM population densities.

Several commenters stated that our analysis of the impacts of LBAM and the effectiveness of natural controls relied on outdated information. One commenter noted that the APHIS petition response cites data from the 1930s to illustrate LBAM damage before the widespread use of organophosphates, but stated that the data is flawed because pesticides in use in the 1930s have general effects similar to the effects of organophosphates, namely eliminating LBAM's natural predators.

APHIS' pest response programs are developed through analysis and evaluation of the invasive pest, including historical information, its behavior in similar environments, and possible control methods. APHIS initiates technical working groups comprised of entomologists from around the world. The LBAM working group, considering different response options, identified a multi-layered response control and suppression strategy including mating disruption, pesticide application, sterile insect technique, and biological control.

Available scientific literature suggests that natural control can be sporadic and incapable of preventing economic losses (Nicholls, 1934; Lloyd *et al.,* 1970; Collyer & van Geldermalsen, 1975; Buchanan, 1977). For example, in the United States, the use of biological control alone generally has not been sufficient to prevent economically significant damage to apple crops by tortricid pests, such as LBAM.

Integrated Pest Management

Several commenters expressed concern that the program has not taken into account non-chemical measures for controlling the LBAM population. One commenter suggested that the integrated fruit production program used in New Zealand to control LBAM be used in California. This program does not use pesticides.

The LBAM program has incorporated integrated pest management (IPM) techniques into the overall LBAM control and suppression strategy. In partnership with industry, universities, and the CDFA, APHIS developed a manual of best management practices to assist the nursery industry in shipping clean products. This manual includes required and recommended practices that help nurseries mitigate LBAM. Examples include establishing physical barriers around nursery perimeters, adopting cultural and sanitation practices, and isolating and protecting inspected plants prior to shipment. The IPM techniques, including principles identified in New Zealand, are used along with mating disruption, sterile insect technique, chemical treatments, and biological control.

Economic Effects

Many commenters expressed concern regarding the economic effects of the LBAM quarantine on domestic growers and stated that the quarantine benefits foreign growers because American growers are required to have LBAM-free fields in order to ship interstate while foreign growers are required to have only LBAM-free shipments. Several commenters expressed concern that organic and small-scale family farms are being forced to either use pesticides, which renders them nonorganic, or shut down their farms.

The purpose of the LBAM quarantine is to protect noninfested areas of the United States from the artificial spread of the moth via the movement of host materials and to keep open export

markets for U.S. products that might otherwise be closed due to the presence of LBAM in the United States. We agree that the introduction of LBAM has led to increased costs for U.S. producers. However, implementation of the regulatory framework has maintained domestic and international markets with, for example, Canada and Mexico, for California agricultural exports. It is likely that some noninfested States would enact restrictions on the movement of host material to safeguard against LBAM spread if there were no Federal program. California producers would then need to meet potentially varying requirements for shipments to each State, which could lead to both increased pesticide use and increased operational costs.

The LBAM program requires that shipments containing LBAM host materials only be free of LBAM prior to movement from the quarantined area; this requirement is parallel to the requirements for foreign shipments. There are several ways for producers to meet this requirement, including applying organic treatments, such as Spinosad and horticultural oils; applying chemical treatments; or implementing best management practices. Such practices include training of staff, scouting and monitoring of property to determine the need for treatments, and maintaining management records.

Many commenters stated that APHIS has overstated the damage done by LBAM and the potential for damage by LBAM; that the LBAM program is expensive and wasteful; and that plants listed as potential LBAM host plants were not hosts of LBAM. Many commenters stated that the only evidence of LBAM damage came from two organic berry fields in 2009, and that it was not conclusively determined that the pest that attacked those fields was LBAM.

APHIS' cost-benefit analysis indicates that if LBAM were to be reclassified as a non-actionable pest and APHIS' regulatory program for LBAM to be terminated, annual sales losses from LBAM damages of at least approximately $694 million would occur (Fowler et al., 2009). Because of the APHIS regulatory program, the amount of avoided losses in annual sales, in comparison with the Federal funding available in the LBAM emergency response effort of almost $100 million, indicates a potential positive benefit-to-cost ratio of at least 6.9 to 1. This does not include potential environmental losses due to factors such as increased pesticide use and other costs associated with widespread establishment of the pest. Additionally, deregulation of LBAM domestically is likely to trigger increased restrictions for LBAM-host commodities by trading partners, which are expected to have a much greater impact on American farms if LBAM were allowed to spread beyond the current quarantined area. The cost-benefit analysis supports our conclusion that LBAM is an economically important invasive pest that meets the criteria for Federal regulation, including phytosanitary regulations and mandatory procedures with the objective of containment and suppression as an actionable quarantine pest.

Miscellaneous

One commenter stated that APHIS was legally required to submit its response to the petitions to reclassify LBAM to NAS for review.

There are no requirements for petition responses to be reviewed by third parties. APHIS elected to submit the revised petition response to NAS.

One commenter supported the continued LBAM quarantine, but stated that the current LBAM program is in need of review because it does not take into account the additional regulatory response that will be needed when LBAM populations expand into other areas of California and the United States. The commenter further stated that the regulations for the movement of cut plant material and nursery stock need to be strengthened. One commenter also supported the continued LBAM quarantine, but stated that APHIS should continually review the quarantine and lift it if the pest is found outside of the quarantined areas and the quarantine becomes uneconomical.

We continually review the LBAM program, as well as other pest programs, to ensure that the program's goals are being met. In the event that LBAM is found within the continental United States outside of California, APHIS and the affected State(s) will take appropriate action, which may include additional detection activities and regulatory protocols, to control its spread.

Therefore, for the reasons discussed in our draft responses to petitions and in this document, we are retaining our classification of LBAM as an actionable quarantine pest to prevent its further spread into noninfested areas of United States and to maintain trade markets for U.S. agricultural products.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02764 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0094]

Notice of Availability of a Treatment Evaluation Document for Heat Treatment for Asian Longhorned Beetle

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that we have determined that it is necessary to add a treatment schedule for Asian longhorned beetle in the Plant Protection and Quarantine Treatment Manual. Thus, we have prepared a treatment evaluation document that discusses the existing treatment schedule and explains why this change is necessary. We are making this treatment evaluation document available to the public for review and comment.

DATES: We will consider all comments that we receive on or before April 11, 2014.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0094-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0094, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0094* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, M.S., Regulatory

Policy Specialist, Regulations, Permits and Manuals, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 135, Riverdale, MD 20737–1236; (301) 851–2352.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in part 305 of 7 CFR chapter III (referred to below as the regulations) set out standards for treatments required in parts 301, 318, and 319 of 7 CFR chapter III for fruits, vegetables, and other articles.

In § 305.2, paragraph (b) states that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual.[1] Section 305.3 sets out a process for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. In that section, paragraph (a) sets out the process for adding, revising, or removing treatment schedules when there is no immediate need to make a change. The circumstances in which an immediate need exists are described in § 305.3(b)(1).

Currently, heat treatment schedule T314–c, which is used as a general treatment for various wood pests, is designated as a treatment for regulated articles moved from an Asian longhorned beetle (ALB) quarantined area. Although effective, we have determined that the treatment temperature and duration prescribed by T314–c are greater than what is necessary to eliminate ALB. In accordance with § 305.3(a)(1), we are providing notice that we have determined that treatment schedule T314–a, which provides a heat treatment schedule for ash logs, including firewood, and all hardwood firewood that are moved from emerald ash borer quarantined areas, is also an effective treatment against ALB. Therefore, we have determined that it is necessary to add ALB to heat treatment schedule T314–a.

[1] The PPQ Treatment Manual is available on the Internet at *http://www.aphis.usda.gov/import_export/plants/manuals/index.shtml* or by contacting the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Manuals Unit, 92 Thomas Johnson Drive, Suite 200, Frederick, MD 21702.

The reasons for this change are described in a treatment evaluation document (TED) we have prepared to support this action. The TED may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may also request paper copies of the TED by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

After reviewing the comments we receive, we will announce our decision regarding the changes to the PPQ Treatment Manual that are described in the TED in a subsequent notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 3rd day of February 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02758 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

White River National Forest; Summit County, CO; Breckenridge Ski Resort Multi-Season Recreation Projects EIS

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: Breckenridge Ski Resort (BSR) has submitted a proposal to the White River National Forest (WRNF) to pursue approval of proposed projects included in its 2013 Master Development Plan (MDP) Addendum. The WRNF has accepted this proposal, and is preparing an Environmental Impact Statement (EIS) to analyze and disclose the potential environmental effects of implementing the projects. The Proposed Action is a range of projects designed to improve year-round recreation opportunities and better meet the changing needs and expectations of visitors to Breckenridge and the WRNF. The proposal hopes to better support a year-round economy in Breckenridge and Summit County by providing a diversity of attractions and outdoor activities that would attract visitors to the area. By providing a greater variety of activities and a longer season to visit BSR, the proposed educational and recreational opportunities would connect a more diverse group of visitors to our National Forest and the outdoors.

DATES: Comments concerning the scope of the analysis must be received by March 12, 2014 The Draft EIS is expected to be available for public review in the Fall/Winter of 2014 and the Final EIS is expected in the Spring/Summer of 2015.

ADDRESSES: Send written comments to: Scott Fitzwilliams, Forest Supervisor, c/o Roger Poirier, Project Leader, 120 Midland Ave, Suite 140, Glenwood Springs, CO 81601; FAX (970) 945–9029 or electronically to: *https://cara.ecosystem-management.org/Public//CommentInput?Project=43291.*

FOR FURTHER INFORMATION CONTACT: Additional information related to the proposed project can be obtained from: Roger Poirier, Project Leader, 120 Midland Ave, Suite 140, Glenwood Springs, CO 81601. Mr. Poirier can be reached by email at *rogierpoirier@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action: Summer recreational opportunities have been offered at BSR since the 1970s. These opportunities are, and continue to be, important to BSR and its guests, in providing outdoor recreation activities in the National Forest in a comfortable setting. The current summer guest experience at BSR is primarily defined by more developed activities on private lands and dispersed activities on National Forest System (NFS) lands. Specific to the activities on NFS lands within the BSR SUP area, guests primarily participate in lift-served and non-lift-served hiking and mountain biking via the Colorado SuperChair and trails dispersed across Peaks 7, 8 and 9.

Through ongoing, year-round tourism growth, BSR is becoming a summer destination for guests primarily from the United States, and from Colorado in particular. In both winter and summer, BSR caters to a broad spectrum of guests of all ages, abilities, and experience with the outdoors. Since 2010 the Peak 8 Fun Park (located on private lands), which includes an alpine slide, a coaster, mini-golf, and other activities, has experienced approximately 18 percent annual growth in its summer activity usage. The proposed projects would complement these current activities by offering an even broader range of passive and active recreation opportunities in the Forest to engage visitors.

The philosophy for BSR's summer program on NFS lands is based on the premise that the National Forests are, and have always been, the greatest opportunity for guests to use and enjoy public lands. The summer program goal is to introduce guests to the White River National Forest and encourage outdoor recreation and enjoyment of nature. BSR desires to provide a fun recreational experience while reducing the barriers that can be associated with recreating in a mountain environment.

Over the past several decades, summer recreation activities have evolved to include a significant variety of activities and user experiences. Likewise, recreational use in the National Forests has evolved beyond the traditional activities and solitude-seeking experiences such as hunting, fishing, camping or hiking.

There is a desire to not only provide new experiences for current Forest users but to provide opportunities that will engage new users to visit and experience NFS lands. Currently at BSR, there is a lack of recreational opportunities that provide:

- Adventure or thrill-based experiences that require little specialized knowledge, skills, equipment or familiarity with the mountain environment—elements which can be a barrier for visitors (e.g. families, the elderly/aging, or those with disabilities) desiring to engage in outdoor activities;
- Activity-based interaction with a forested, mountain environment in a controlled setting, offering an opportunity for users to interact with and learn about nature;
- Human-powered, active recreational experiences that cater to all ability levels; and
- Interpretive programs that offer an educational experience for users seeking to learn more about the environment.

There is a need for recreational and learning opportunities on public lands that include passive, active and interactive forms of recreation to provide this comprehensive range of user experiences.

In addition, there is a need for adequate access and support service infrastructure (e.g. roads, support buildings, restaurants) to meet current and anticipated summer use at BSR.

The Ski Area Recreational Opportunity Enhancement Act of 2011 (SAROEA) provides authority for mountain resorts operating on NFS lands to offer an expanded range of outdoor recreation activities in order to further recreational opportunities for the public, allow year-round utilization of existing resort facilities and stimulate job creation and economic growth within local communities. The proposed projects align with the intent of SAROEA.

Proposed Action: The Proposed Action includes the following seventeen elements, identified below. A full description of each element can be found at: *http://www.fs.fed.us/nepa/fs-usda-pop.php/?project=43291.*

- Improve natural aesthetic look and feel of the Vista Haus and Independence SuperChair Summit Site Plan with landscaping, access pathways, signage, and possible road realignments.
- Install the Sawmill Zip Line from a location south of the top terminal of the Peak 8 SuperConnect to its endpoint near the top terminal of the Snowflake lift.
- Install the Peak 7 Zip Line from a location near the top terminal of the Independence SuperChair to its endpoint near the Peak 7 base area.
- Install the Sawmill Canopy Tour from a location near the Vista Haus to an endpoint along Four O'Clock ski trail. The canopy tour would utilize a series of approximately nine zip lines and ten canopy tour stations.
- Install the Ore Bucket Canopy Tour from a location just west (uphill) of the Independence SuperChair to the Angels Rest ski trail and the 7/8 Access Road on Peak 7. The canopy tour would utilize a series of approximately 9 zip lines and 10 stations.
- Install the Claimjumper Canopy Tour on Peak 7 near the upper 1/3 portion of the Independence SuperChair and Claimjumper ski trail. BSR will complete the layout of this canopy tour and provide the information to the Forest Service for analysis in the Draft EIS.
- Construct two challenge courses featuring a series of wooden columns, platforms and rope walkways/bridges adjacent to the Vista Haus on Peak 8 with one course geared towards children under 10 and a second for older guests.
- New and Realigned Mountain Bike Trails and Skills Courses are proposed on Peak 7 to connect to and expand on the existing trail network on Peak 8 and 9. The proposal includes the creation of beginner skills courses on Peak 7 and 8.
- Construct approximately 2 miles of new dispersed and guided hiking trails, including way-finding and interpretive sites.
- Initiate new off-highway vehicle tours on existing and proposed roads for additional sightseeing opportunities.
- Realign Four O'Clock Road to remove the excessive grade by adding switchbacks and adding roughly half a mile of new roadway.
- Expand the Peak 7 Hut Deck/Building to add approximately 500 square feet to the building and expanded outside deck to better provide space for guests and operations.
- Expand the Vista Haus Deck to add approximately 1,500 square feet on the south side of the lodge and would accompany the construction of a climbing wall.
- Construct an observation tower on Peak 8 approximately 30 feet in height.
- Operate the existing Colorado SuperChair, Independence SuperChair, 6 Chair and Imperial Express SuperChair for scenic lift rides and activities access.
- Implement summer uses restoration projects in response to existing and proposed disturbed areas within and potentially beyond the SUP boundary. These projects would be developed subsequent to scoping and would be analyzed in the Draft EIS.

These projects are proposed to expand opportunities for developing year-round recreational activities, and improve Breckenridge's year-round economy by attracting a wide range of visitors, of all ages, abilities, and familiarity with the outdoors, to our National Forest.

Responsible Official: The Responsible Official is Scott Fitzwilliams, Forest Supervisor for the WRNF.

Nature of Decision To Be Made: Based on the analysis that will be documented in the forthcoming EIS, the Responsible Official will decide whether or not to implement, in whole or in part, the Proposed Action or another alternative that may be developed by the Forest Service as a result of scoping.

Scoping Process: This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. The Forest Service is soliciting comments from Federal, State and local agencies and other individuals or organizations that may be interested in or affected by implementation of the proposed projects. A public open house regarding this proposal will be held at Mountain Thunder Lodge (50 Mountain Thunder Drive, Breckenridge, CO 80424) on March 5, 2014 between 4:30 and 6:30 p.m. Representatives from the WRNF and BSR will be present to answer questions and provide additional information on this project.

Public questions and comments regarding this proposal are an integral part of this environmental analysis process. Input provided by interested and/or affected individuals, organizations and governmental agencies will be used to identify resource issues that will be analyzed in the environmental impact statement.

The Forest Service will identify significant issues raised during the scoping process, and use them to formulate alternatives, prescribe mitigation measures and project design features, or analyze environmental effects.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however.

Dated: February 4, 2014.

Jan Cutts,

District Ranger.

[FR Doc. 2014–02778 Filed 2–7–14; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), the Rural Utilities Service (RUS) invites comments on this information collection for which RUS intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by April 11, 2014.

FOR FURTHER INFORMATION CONTACT: Michele L. Brooks, Director, Program Development and Regulatory Analysis, USDA Rural Development, 1400 Independence Ave. SW., STOP 1522, Room 5162 South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. FAX: (202) 720–8435. Email: *Michele.Brooks@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Michele L. Brooks, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., STOP 1522, Room 5162 South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078, FAX: (202) 720–8435. Email: *Michele.Brooks@wdc.usda.gov.*

Title: 7 CFR Part 1744, Subpart B, "Lien Accommodations and Subordination Policy"

OMB Control Number: 0572–0126

Type of Request: Extension of a currently approved information collection.

Abstract: Recent changes in the telecommunications industry, including deregulation and technological developments, have caused RUS borrowers and other organizations providing telecommunications services in rural areas to consider undertaking projects that provide new telecommunications services and other telecommunications services not ordinarily financed by RUS. Although some of these services may not be eligible for financing under the Rural Electrification Act of 1936 (RE Act), these services may nevertheless advance RE Act objectives where the borrower obtains financing from private lenders. To facilitate the financing of those projects and services, this program helps to facilitate funding from non-RUS sources in order to meet the growing capital needs of rural Local Exchange Carriers (LECs).

The information collected for lien accommodation requests is used by RUS to ascertain a borrower's level of financial strength and, upon agency approval of the lien accommodation, ensures that the government's loan security interest is protected.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .50 hour per response.

Respondents: Business or other for-profit and non-profit institutions.

Estimated Number of Respondents: 3.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 2.

Copies of this information collection can be obtained from MaryPat Daskal, Program Development and Regulatory Analysis, at (202) 720–7853, FAX: (202) 720–8435. Email: *MaryPat.Daskal@wdc.usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: January 13, 2014.

John Charles Padalino,

Administrator, Rural Utilities Service.

[FR Doc. 2014–02807 Filed 2–7–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–009–2014]

Foreign-Trade Zone 104—Savannah, Georgia, Application for Reorganization (Expansion of Service Area), Under the Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the World Trade Center Savannah, LLC, grantee of FTZ 104, requesting authority to expand its service area under the alternative site framework (ASF) adopted by the Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on February 4, 2014.

FTZ 104 was approved by the Board on April 18, 1984 (Board Order 256, 49 FR 17789, 04/25/84) and reorganized

under the ASF on January 12, 2011 (Board Order 1736, 76 FR 4865, 1/27/11, and the service area was expanded on June 10, 2013 (Board Order 1904, 78 FR 36165, 6/17/13). The zone currently has a service area that includes the counties of Bulloch, Bryan, Chatham, Effingham, Evans, Liberty, Long, Screven, Columbia and Richmond.

The applicant is requesting authority to expand the service area of the zone to include Burke, Candler, Emanuel, Jefferson, Jenkins, Johnson, Laurens, Montgomery, Tattnall, Telfair, Toombs, Treutlen, Washington and Wheeler Counties, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Savannah Customs and Border Protection port of entry.

In accordance with the Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 11, 2014. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 28, 2014.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *www.trade.gov/ftz*. For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: February 4, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–02835 Filed 2–7–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967]

Aluminum Extrusions From the People's Republic of China: Correction of the Final Results of Antidumping Duty Administrative Review and Rescission, in Part, 2010/12

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

DATES: Effective January 2, 2014.

FOR FURTHER INFORMATION CONTACT: Paul Stolz or Demitrios Kalogeropoulos, AD/CVD Operations, Office III, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4474 or (202) 482–2623, respectively.

Correction

On January 2, 2014, the Department of Commerce ("the Department") published the *Final Results* of the first administrative review of the antidumping duty order on aluminum extrusions from the People's Republic of China.[1] The published **Federal Register** notice contained a ministerial error in that it included an exporter's name (*i.e.*, "Zhongshan Gold Mountain Aluminum Factory Ltd."[2]) that was misspelled. The correct spelling of this exporter's name is Zhongshan Gold Mountain Aluminium Factory Ltd. Pursuant to section 751(h) of the Tariff Act of 1930, as amended ("the Act"), the Department shall correct any ministerial errors within a reasonable time after the determinations are issued under this section. A ministerial error is defined as an error "in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error. . . ." This notice serves to correct the incorrect exporter company name listed in the *Final Results*.

This correction is published in accordance with sections 751(h) and 777(i) of the Act.

[1] *See Aluminum Extrusions From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Rescission, in Part, 2010/12*, 79 FR 96 (January 2, 2014) ("*Final Results*").

[2] *Id.*, 79 FR 100.

Dated: January 31, 2014.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2014–02836 Filed 2–7–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–870]

Chlorinated Isocyanurates From Japan: Postponement of Preliminary Determination of Antidumping Duty Investigation

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

DATES: February 10, 2014.

FOR FURTHER INFORMATION CONTACT: Julia Hancock or Jerry Huang, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–1394, or (202) 482–4047, respectively.

SUPPLEMENTARY INFORMATION:

Postponement of Preliminary Determination

On September 25, 2013, the Department of Commerce (the "Department") initiated an antidumping duty investigation on chlorinated isocyanurates from Japan.[1] The *Initiation Notice* stated that the Department, in accordance with section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the "Act"), and 19 CFR 351.205(b)(1), would issue its preliminary determination for this investigation, unless postponed, no later than 140 days after the date of the initiation.[2] In addition, the Department tolled deadlines by 16 days due to the shutdown of the Federal Government.[3] Thus, the preliminary determination of this antidumping duty investigation is currently due no later than February 21, 2014.

On January 15, 2014, more than 25-days before the scheduled preliminary determination, Clearon Corp. and Occidental Chemical Corporation

[1] *See Chlorinated Isocyanurates from Japan: Initiation of Antidumping Duty Investigation*, 78 FR 58997 (September 25, 2013) ("*Initiation Notice*").

[2] *Id.*, 78 FR 59000.

[3] *See* "Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, Deadlines Affected by the Shutdown of the Federal Government," dated October 18, 2013.

(hereinafter referred to as "Petitioners") made a timely request for a 50-day postponement of the preliminary determination in this investigation, pursuant to section 733(c)(1)(A) of the Act and 19 CFR 351.205(e).[4] Petitioners noted in their request that they require additional time to analyze and comment upon the questionnaire responses of the mandatory respondents in this investigation.

The Department has found no compelling reason to deny the request and, therefore, in accordance with section 733(c)(1)(A) of the Act, the Department is postponing the deadline for the preliminary determination to no later than 206 days after the date on which it initiated this investigation (the original 140-day period plus the 16 days tolled for the shutdown of the Federal Government and a 50 day postponement). Therefore, the new deadline for issuing the preliminary determination is April 14, 2014.[5] In accordance with section 735(a)(1) of the Act, the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: January 24, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–02837 Filed 2–7–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–840]

Lightweight Thermal Paper From Germany: Preliminary Results of the First Full Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On October 1, 2013, the Department of Commerce (the Department) initiated the first five-year (sunset) review of the antidumping duty (AD) order on lightweight thermal paper from Germany pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] On the basis of adequate substantive responses submitted by domestic and respondent interested parties, the Department is conducting a full sunset review of this AD order pursuant to section 751(c) of the Act and 19 CFR 351.218(e)(2). As a result of our analysis, the Department preliminarily finds that revocation of the AD order would likely lead to continuation or recurrence of dumping at the levels indicated in the "Preliminary Results of Review" section of this notice. Interested parties are invited to comment on these preliminary results.

DATES: Effective February 10, 2014.

FOR FURTHER INFORMATION CONTACT: David Goldberger, AD/CVD Operations, Office II, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4136.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2013, the Department initiated the first sunset review of the AD order on lightweight thermal paper from Germany pursuant to section 751(c) of the Act.[2] On October 28, 2013, the Department received a notice of intent to participate from Appvion, Inc. (Appvion [3]), a domestic manufacturer of lightweight thermal paper within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i).[4]

On November 18, 2013, the Department received substantive responses from Appvion and Papierfabrik August Koehler SE (Koehler), a German producer of lightweight thermal paper, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). The Department received rebuttal comments from Appvion and Koehler on November 25, 2013 in accordance with 19 CFR 351.218(d)(4).

On December 4, 2013, the Department issued its adequacy determination memorandum. The Department found that Appvion and Koehler submitted adequate substantive responses. As a result, the Department is conducting a full sunset review of this AD order.[5] The Department did not receive comments on the adequacy determination memorandum from any party to this review.

Scope of the Order

The merchandise covered by the order is lightweight thermal paper. The merchandise subject to the order is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 3703.10.60, 4811.59.20, 4811.90.8000, 4811.90.8030, 4811.90.8040, 4811.90.8050, 4811.90.9000, 4811.90.9030, 4811.90.9035, 4811.90.9050, 4811.90.9080, 4811.90.9090, 4820.10.20, and 4823.40.00. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

For a full description of the scope, see "Preliminary Results Issues and Decision Memorandum for the Full Sunset Review of the Antidumping Duty (AD) Order on Lightweight Thermal Paper from Germany," dated concurrently with this notice (Decision Memorandum).

Analysis of Comments Received

All issues raised in this review are addressed in the Decision Memorandum, dated concurrently with this preliminary notice, which is hereby adopted by this notice. The issues discussed in the accompanying Decision Memorandum include the likelihood of the continuation of dumping, the magnitude of the margin likely to prevail, and good cause to examine other factors. Parties can find a complete discussion of all issues raised in this full sunset review and the corresponding recommendations in this

[4] *See* Letter from Petitioners to the Secretary of Commerce, "Antidumping Duty Investigation of Chlorinated Isocyanurates from Japan—Petitioners' Request for Extension of Time for Preliminary Determination," dated January 15, 2014.

[5] The postponed deadline, calculated as 190 days from September 25, 2013 (the date of publication of the *Initiation Notice*) plus the 16 days tolled for the shutdown of the Federal Government, falls on April 12, 2014, a Saturday, which is not a business day. Therefore, the postponed deadline is the next business day, which is Monday, April 14, 2014. *See Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended.* 70 FR 24533 (May 10, 2008).

[1] *See Initiation of Five-Year ("Sunset") Review,* 78 FR 60253 (October 1, 2013) (*Sunset Initiation*).

[2] *See Sunset Initiation.*

[3] Appvion (formerly Appleton Papers) was the petitioner in the original investigation of lightweight thermal paper from Germany. *See Lightweight Thermal Paper from Germany: Notice of Final Determination of Sales at Less Than Fair Value,* 73 FR 57326 (October 2, 2008) (*LTFV Final*).

[4] As explained in the memorandum from the Assistant Secretary for Enforcement and Compliance, the Department exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 1, through October 16, 2013. *See* Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Shutdown of the Federal Government" (October 18, 2013). Therefore, all deadlines in this sunset review have been extended by 16 days.

[5] *See* Memorandum from Team to James Maeder, Director, Antidumping and Countervailing Duty Operations, Office II, titled "Adequacy Determination in Five-Year 'Sunset' Review of the Antidumping Duty Order on Lightweight Thermal Paper from Germany (2008–2012)" (December 4, 2013).

public memorandum, which is on file in the Department's Central Records Unit. In addition, a complete version of the Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/index.html.* The paper copy and electronic version of the Decision Memorandum are identical in content.

Preliminary Results of Review

We preliminarily determine that revocation of the AD order on lightweight thermal paper from Germany would be likely to lead to continuation or recurrence of dumping at the following weighted-average margins:

Manufacturer/exporter	Margin (percent)
Koehler	6.50
All Others	6.50

Interested parties may submit case briefs no later than 50 days after the date of publication of the preliminary results of this full sunset review, in accordance with 19 CFR 351.309(c)(1)(i). Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than the five days after the time limit for filing case briefs in accordance with 19 CFR 351.309(d).

Any interested party may request a hearing within 30 days of publication of this notice in accordance with 19 CFR 351.310(c). A hearing, if requested, will be held on a date to be determined.

The Department intends to issue a notice of final results of this full sunset review, which will include the results of its analysis of issues raised in any briefs, no later than May 29, 2014.

We are issuing and publishing the preliminary results and notice of this full sunset review in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218(f)(1).

Dated: February 4, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–02838 Filed 2–7–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 99–7A005]

Export Trade Certificate of Review

ACTION: Notice of Application (99–7A005) to amend the Export Trade Certificate of Review held by California Almond Export Association, LLC ("CAEA").

SUMMARY: The Office of Trade and Economic Analysis ("OTEA") of the International Trade Administration, Department of Commerce, has received an application to amend an Export Trade Certificate of Review ("Certificate"). This notice summarizes the proposed amendment and requests comments relevant to whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) ("the Act") authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (2014).

OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the application in the **Federal Register**. Under 15 CFR 325.6(a), interested parties may, within twenty days after the date of this notice, submit written comments to the Secretary on the application.

Summary of the Application

Applicant: California Almond Export Association, LLC ("CAEA"), 4800 Sisk Road Modesto, CA 95356.

Contact: Bill Morecraft, Chairman, Telephone: (916) 446–8537.

Application No.: 99–7A005.

Date Deemed Submitted: January 29, 2014.

Proposed Amendment: CAEA seeks to amend its Certificate to delete the following company as a Member of CAEA's Certificate: Treehouse California Almonds, LLC, Los Angeles, CA.

CAEA's proposed amendment of its Export Trade Certificate of Review would result in the following companies as Members under the Certificate:

Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Blue Diamond Growers, Sacramento, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Inc., Livingston, CA
Fair Trade Corner, Inc., Chico, CA
Fisher Nut Company, Modesto, CA
Hilltop Ranch, Inc., Ballico, CA
Hughson Nut, Inc., Hughson, CA
Mariani Nut Company, Winters, CA
Minturn Nut Company, Inc., LeGrand, CA
Nutco, LLC d.b.a. Spycher Brothers, Turlock, CA
Paramount Farms, Inc., Los Angeles, CA
P–R Farms, Inc., Clovis, CA
Roche Brothers International Family Nut Co., Escalon, CA
South Valley Almond Company, LLC, Wasco, CA
Sunny Gem, LLC, Wasco, CA
Western Nut Company, Chico, CA

Dated: February 4, 2014.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration.

[FR Doc. 2014–02733 Filed 2–7–14; 8:45 am]

BILLING CODE 3510–DR–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2011–0074]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; CPSC Table Saw User Survey

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) is announcing that a proposed collection of information regarding a survey of table saw users to determine the effectiveness of modular blade guards has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by March 12, 2014.

ADDRESSES: OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified by Docket No. CPSC–2011–0074. In addition, written comments also should be submitted at *http://www.regulations.gov,* under Docket No. CPSC–2011–0074, or by mail/hand delivery/courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923. For access to the docket to

read background documents or comments received, go to *http://www.regulations.gov.* The draft survey may be viewed under Docket No. CPSC–2011–0074, Supporting and Related Materials.

FOR FURTHER INFORMATION CONTACT: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

A. Table Saw User Survey

The CPSC is considering whether a new performance safety standard is needed to address an unreasonable risk of injury associated with table saws. On October 11, 2011, the Commission published an advance notice of proposed rulemaking (ANPR) for table saws, under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051–2084. (76 FR 62678). The ANPR explained that under the current voluntary standard, UL 987, Stationary and Fixed Electric Tools, published in November 2007, a new modular blade guard design, developed by a joint venture of table saw manufacturers, expanded the table saw guarding requirements. The new blade guard did not consist of a hood, but rather, a top-barrier guarding element and two side-barrier guarding elements. The new modular guard design was intended by UL to provide safety improvements over traditional hood guard designs, by providing better visibility, by being easier to remove and install, and by incorporating a permanent riving knife design. The revised standard also specified detailed design and performance requirements for the modular blade guard, riving knife, and anti-kickback device(s). The effective date for the new requirements in UL 987 was January 31, 2010.

In the ANPR, the Commission expressed concern that the requirements in the voluntary standard for table saws, UL 987, which include a permanent riving knife and the new modular blade guard system, may not adequately address the operator blade contact injuries associated with table saw use. The Commission stated that:

> While we support the recent progress UL has made in improving the voluntary standard to address blade contact injuries by focusing solely on prevention of skin-to-blade contact, the standard requirements do not appear to address adequately the number or severity of blade contact injuries that occur on table saws, nor do they address the associated societal costs. In addition, while we believe that the new modular guard design is a significant improvement over the old guard design, the effectiveness of any blade guard system depends upon an operator's willingness to use it. Safety equipment that hinders the ability to operate the product likely will result in consumers bypassing, avoiding, or discarding the safety equipment. In addition, of the 66,900 table saw operator blade contact injuries in 2007 and 2008, approximately 20,700 (30.9%) of the injuries occurred on table saws where the blade guard was in use. The current voluntary standard for table saws does not appear to address those types of injuries. Accordingly, we are particularly interested in obtaining information regarding current or developing voluntary standards that would address table saw blade contact injuries.
>
> 76 FR 62683.

Currently, the CPSC does not have information about actual use by consumers of the new modular blade guard. Because the usage patterns are directly linked to the safety of the user, additional data are needed to understand how consumers use the modular blade guard to determine how effective the design will be in preventing future injuries.

The data collected from this survey will be used to help CPSC staff understand better how consumers are using the modular blade guard system, such as when consumers install and remove the blade guard, what type of cuts are being made without the blade guard, and/or what may be preventing the use of the blade guard. With additional information, the Commission will be able to evaluate better the role of modular blade guards on table saws. The data, along with other available test results and studies will be reviewed by the Commission in its consideration of whether a new performance safety standard is needed to address an unreasonable risk of injury associated with table saws.

To gather the information, the CPSC will conduct a survey of consumers who own table saws with a modular blade guard system. Because the population of owners of table saws that were purchased with a modular blade guard is a specific and hard-to-reach population, the survey will be based on a convenience sample of participants recruited by various advertisement strategies. A convenience sample is a non-probability sample, which is collected by the most efficient means of reaching a group of interest. No results from the survey will be generalized to the population or used to draw statistical inferences.

To recruit respondents, advertisements will be placed on popular Web sites, in woodworking magazines, and posted in woodworking guilds with their cooperation. Respondents will have the option of going through a screening process, either online, or via telephone. Respondents meeting the criteria of the survey—owners of table saws with the modular blade guard system—will participate in the follow-up, full-scale Computer Assisted Telephone Interviewing (CATI) survey about their usage of, and opinions about, the modular blade guard system.

CPSC staff anticipates that approximately 200 eligible respondents will complete the CATI interview survey. After completion of the full-scale CATI survey, each respondent will be sent a $50 check for completing the survey. A final report will summarize the data about modular blade use collected from the surveyed table saw owners. Any patterns that emerge may also be used by CPSC staff to develop future studies.

On May 28, 2013, the Commission sought comments on the proposed collection of information through a survey to obtain information from consumers (respondents) who own table saws with a modular blade guard system. 78 FR 31897.

B. Comments

The Commission received five comments on the table saw survey. One commenter generally supported the survey. One commenter raised an issue regarding the SawStop technology but did not raise any issues related to the survey. That comment is outside the scope of the notice regarding the proposed information collection and will be treated as a comment to the ANPR. Comments were also submitted by Stephen Gass, the manufacturer of SawStop table saws, and the Power Tool Institute (PTI). PTI made two submissions. On May 13, 2013, prior to the publication of the May 28, 2013 notice, PTI submitted its own draft survey to the Commission for consideration. On July 26, 2013, PTI submitted comments on the CPSC's proposed survey.

The Commission will continue to use the survey sponsored by the CPSC, which is tailored to address the CPSC staff's questions on table saw modular blade guard use. However, several changes have been made to the CPSC's survey, in response to comments from Mr. Gass and PTI, as discussed below.

1. Injury Data

Comment: Mr. Gass states that to understand usage of the modular blade guard system, injured users should be surveyed to determine whether the injury occurred with the new modular

blade guard system or an older guard. According to Mr. Gass, if the new guards are truly effective, there should be a commensurate drop in the number of table saw injuries in the National Electronic Surveillance System (NEISS).

Response: A reduction in injuries is the most direct way of assessing the effectiveness of the new modular blade guard. However, the currently available injury data do not provide that information. For example, NEISS data on table saw-related injuries do not indicate whether a blade guard was used, what type of blade guard was used, or how the blade guards were used. The CPSC has conducted a special study on injuries associated with table saws in 2007 and 2008. However, the addition of the revised modular blade guard system is a recent development and another special study is unlikely to gather sufficient data to assess the efficacy of the modular blade guard in injury prevention. Through the proposed survey, CPSC staff believes that more information regarding the use of the modular blade guard will become available, will supplement existing CPSC information and data, and will assist the Commission in identifying addressable hazards related to table saw use.

2. Definitions

Comment: Both Mr. Gass and PTI state that clear definitions must be provided to all participants to identify properly the table saw used by the participant.

Response: To identify the respondent's saw better, the revised survey provides that clear definitions of table saws (bench top portable bench saw, contractor saw, stationary saw) will be provided to all participants.

3. Number of Respondents

Comment: Although PTI states that some useful information may be developed, PTI questions the utility of a survey that has only 100 respondents, if the information is intended for use in developing a rule.

Response: The primary goal of the survey is to help CPSC staff understand if and how the modular blade guard system is used by consumers. The principal benefit of the survey is to provide the Commission with important information about table saw use that is now lacking and would not be obtainable other than through such a survey. The survey now seeks two hundred responses (up from the 100 respondents initially sought), which will greatly expand the quantity and scope of existing information and significantly inform staff's evaluation of modular blade guard systems. To the extent that other studies, tests, or surveys have been performed to analyze table saw blade contact injuries, the Commission would review all available data in its consideration of whether a new performance safety standard is needed to address an unreasonable risk of injury associated with table saws.

The population sought in the survey is a specific subset of all table saw users and is a hard-to-reach population. The survey seeks consumers who purchased table saws with a modular blade guard within the last 4 years (from 2009 and the present). Table saws purchased before 2009 do not meet the needs of the study; and the consumers who purchased table saws before 2009 will constitute a significant portion of current table saw owners. Accordingly, this survey will be based on a convenience sample of recruited participants by various advertisement strategies. No results from this study will be generalized to the population.

4. Years Covered by the Survey

Comment: According to PTI, the screener and survey should cover years before 2009 because table saws with modular guards were on the market as of 2007.

Response: Due to the limited number of table saws sold before 2009 with a modular blade guard, the cost of recruiting participants would increase greatly if the survey were expanded to add table saws purchased before 2009. Few table saws had modular blade guards before 2009, so significant additional data are not likely to be obtained from the period between 2007 and 2009. Because many more table saws manufactured in 2009 and later were sold with modular blade guards, the survey covers 2009 to the present.

5. New vs. Old Table Saws

Comment: PTI states that the survey should focus only on new table saws purchased or received as a gift and that all questions regarding used table saws or table saws without modular blade guards should be removed.

Response: The survey will not be limited to new table saws because there is a secondhand market for table saws. The survey seeks to obtain information on how table saw owners are using (or not using) their modular blade guard system. If table saw users are not using their modular blade guard system because they did not purchase, install, or receive one, that information is useful to CPSC staff. Similarly, if the lack of instructions prevents the user from installing and using the modular blade guard system, that information also will assist CPSC staff in understanding the use patterns of the modular blade guard system.

6. Screener Should Apply To All Woodworkers

Comment: PTI states that the table saw survey should not terminate if the participant is using the saw only at work or at wood working facilities. According to PTI, the survey already establishes that the table saw is owned by the participant and not by the participant's employer or by a third party.

Response: Many table saw owners are consumers who may use the table saw to perform work and for recreation. These participants are invited to complete the screener questions and survey, if applicable. However, if the table saw owner is using the table saw for work purposes only, or in a commercial woodworking facility, those woodworkers fall outside the scope of the survey, which is intended to assess how consumers would use the modular blade guard system.

7. Other Clarifications to the Screener/ Survey

Comment: PTI contends that the survey questions regarding table saw use and installation or removal of the modular blade guard require additional clarification or revision. PTI states that a more accurate picture of the traditional guarding system should be used in the table saw screener. In addition, PTI states that questions comparing modular blade guards to traditional blade guards should be removed or clarified.

Response: In response to this comment, many of the questions related to the blade guard and certain types of cuts have been revised. A new picture of the traditional guard has been added, as suggested by the commenter. The questions have been clarified to specify the use and removal of the blade guard for both through or non-through cuts. In addition, other questions have been removed, including questions that were ambiguous or unrelated to the use of the modular blade guard system, such as questions on kickback and riving knife use. However, the survey does not modify questions comparing the use of the modular blade guard to the traditional blade guard because these questions ascertain overall attitudes for general blade guard use, and there is no need to distinguish between through cuts or non-through cuts for these questions.

B. Burden Hours

CPSC staff estimates that the recruitment stage time required to verify whether a respondent fits the study's target group of consumers will not exceed 10 minutes, and the actual survey will not exceed 25 minutes. Thus, total time per eligible respondent is estimated not to exceed 35 minutes. For the 200 anticipated eligible respondents, (which is up from the 100 respondents originally targeted) the total time required in connection with the survey would be estimated at approximately 116 hours (200 x 0.58 hours) in the aggregate. According to the Bureau of Labor Statistics, September 2013 (updated from March 2013), the average hourly compensation rate for all workers is $29.23. The total cost burden to respondents for this study is estimated at $3,391.

The estimated cost under the federal government contract is $276,585 for the costs of recruiting respondents and conducting the survey. In addition, one full-time CPSC employee will spend an estimated 600 hours of labor reviewing responses for a total estimated cost of $49,488, the equal to 600 hours at an hourly compensation rate of $57.08 for a GS–14 Step 5 employee, with an additional 30.8 percent added for benefits for a total hourly compensation rate of $82.48. (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," December 2012, Table 1, percentage of wages and salaries for all civilian management, professional, and related employees, *http://www.bls.gov/ncs*). Accordingly, the total estimated cost to the federal government is $326,073 ($276,585 plus $49,488).

Dated: February 5, 2014.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2014–02786 Filed 2–7–14; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2014–OS–0019]

Privacy Act of 1974; Notice of a Computer Matching Program

AGENCY: Defense Manpower Data Center, DoD.

ACTION: Notice of a computer matching program.

SUMMARY: Subsection (e)(12) of the Privacy Act of 1974, as amended, requires agencies to publish advance notice of any proposed or revised computer matching program by the matching agency for public comment. The Department of Defense (DoD), as the matching agency under the Privacy Act is hereby giving notice to the record subjects of a computer matching program between the Department of Defense (DoD) and the Office of Personnel Management (OPM) that their records are being matched by computer. The purpose of this agreement is to establish the conditions, safeguards, and procedures under which the OPM, as the source agency, will disclose Federal Employees Health Benefits (FEHB) program eligibility and Federal employment information to DoD, as the recipient agency. This disclosure by OPM will provide the DoD with the FEHB program eligibility and Federal employment information necessary to either verify the eligibility to enroll or verify the continuing eligibility of enrolled Service members for premium based TRICARE health plans such as the TRICARE Reserve Select (TRS) and the TRICARE Retired Reserve (TRR).

DATES: This proposed action will become effective March 12, 2014 and matching may commence unless changes to the matching program are required due to public comments or by Congressional or by Office of Management and Budget objections. Public comments must be received before March 12, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Samuel P. Jenkins at telephone (703) 571–0070.

SUPPLEMENTARY INFORMATION: Pursuant to subsection (o) of the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Defense Manpower Data Center (DMDC) and OPM have concluded an agreement to conduct a computer matching program between the agencies. The purpose of this match is for determining the eligibility for the FEHB program and the eligibility for enrollment in premium based TRICARE health plans for Reserve Component (RC) Service members. The parties to this agreement have determined that a computer matching program is the most efficient, expeditious, and effective means of obtaining the information needed by the OPM to identify individual's ineligible to continue the TRICARE Reserve Select and TRICARE Retired Reserve (TRR) Programs. If this identification is not accomplished by computer matching, but is done manually, the cost would be prohibitive and it is possible that not all individuals would be identified. A copy of the computer matching agreement between OPM and DMDC is available upon request to the public. Requests should be submitted to Acting Director, Defense Privacy and Civil Liberties Office, 241 18th Street South, Suite 101, Arlington, VA 22202 or to the Office of Personnel Management, 1900 E Street NW., Room 5415, Washington, DC 20415. Set forth below is the notice of the establishment of a computer matching program required by paragraph 6.c. of the Office of Management and Budget Guidelines on computer matching published in the **Federal Register** at 54 FR 25818 on June 19, 1989.

The matching agreement, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, and an advance copy of this notice was submitted on February 3, 2014, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget pursuant to paragraph 4d of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," February 8, 1996 (February 20, 1996; 61 FR 6427).

Dated: February 5, 2014.

Aaron Siegel, Alternate OSD Federal Register Liaison Officer, Department of Defense.

Notice of a Computer Matching Program Between the Department of Defense (DOD), Defense Manpower Data Center (DMDC)

A. *Participating Agencies:* Participants in this computer matching program are the Office of Personnel Management (OPM) and the Defense Manpower Data Center (DMDC) of the Department of Defense (DoD). The OPM is the source agency, i.e., the activity disclosing the records for the purpose of

the match. The DMDC is the specific recipient activity or matching agency, i.e., the agency that actually performs the computer matching.

B. *Purpose of the Match:* Establishes the conditions, safeguards, and procedures under which the OPM, as the source agency, will disclose FEHB program eligibility and Federal employment information to DoD, as the recipient agency. This disclosure by OPM will provide the DoD with the FEHB program eligibility and Federal employment information necessary to either verify the eligibility to enroll or verify the continuing eligibility of enrolled Service members for premium based TRICARE health plans such as the TRICARE Reserve Select (TRS) and the TRICARE Retired Reserve (TRR).

C. *Legal Authority:* This CMA is executed to comply with section 552a of Title 5, United States Code (U.S.C.), as amended (the Privacy Act of 1974), Public Law (Pub. L.) 100–503, the Computer Matching and Privacy Protection Act (CMPPA) of 1988, the Office of Management and Budget (OMB) Circular A–130, titled "Management of Federal Information Resources" at 61 **Federal Register** (FR) 6435, February 20, 1996, and OMB guidelines pertaining to computer matching at 54 FR 25818, June 19, 1989. Section 706 of Public Law 109–364, the John Warner National Defense Authorization Act of 2007, amended section 1076d of Title 10, U.S.C. to established the enhanced TRS health plan as of October 1, 2007. Section 705 of Public Law 111–84, National Defense Authorization Act for Fiscal Year 2010, amended section 1076e of Title 10, U.S.C. to establish the TRR health plan as of October 29, 2009. RC Service members who have continuing eligibility for the FEHB program pursuant to chapter 89 of Title 5, U.S.C. are not eligible to enroll, or continue an enrollment, in the TRS or the TRR program. This agreement implements the additional validation processes needed by DoD to insure RC Service members eligible for the FEHB program may not enroll, or may not continue a current enrollment, in the TRS or the TRR health plan.

D. *Records To Be Matched:* Systems of Records (SOR). DoD will use the SOR identified as DMDC 02 DoD, entitled "Defense Enrollment Eligibility Reporting System (DEERS), November 21, 2012, 77 FR 69807." The SSNs of RC Service members released to OPM pursuant to the routine use "20a" set forth in the system notice DMDC 02 DoD. Systems of Records (SOR). OPM provides identification of the FEHB program status of RC Service members to validate the eligibility for the statutory requirement of the TRS and the TRR program. Therefore, eligibility information is maintained in the SOR identified as OPM/GOVT–1 entitled "General Personnel Records, December 11, 2012, 77 FR 79694.

E. *Description of Computer Matching Program:* Under the terms of this matching agreement, the Defense Manpower Data Center (DMDC) will provide to OPM a file of records consisting of Social Security Number (SSN), date of birth (DOB), and the name of Service members of the Ready Reserve, Standby Reserve, and Retired Reserve of the Armed Forces of the United States. DMDC will update the Defense Enrollment Eligibility Reporting System (DEERS) record of those RC Service members with FEHB program eligibility information from the OPM response file. The Office of the Assistant Secretary of Defense for Reserve Affairs (OASD(RA)) will be responsible for providing the verified information to the RCs to aid in processing of TRS and TRR eligibility determinations. OPM agrees to conduct two computer matches within a calendar year of the records of RC Service members provided by DMDC matched with the information found in OPM's Enterprise Human Resources Integration (EHRI) system for permanent employees in a current pay status. OPM will validate the identification of the RC records that match with the name, SSN and DOB provided by DMDC. OPM will provide the Civilian Agency Indicator, the full FEHB Program Plan Code, a Multiple Record Indicator, and a DOB Match Indicator. OPM will forward a response file to DMDC within 30 business days following the receipt of the initial finder file and for all subsequent files submitted.

F. *Inclusive Dates of the Matching Program:* This computer matching program is subject to public comment and review by Congress and the Office of Management and Budget. If the mandatory 30 day period for comment has expired and no comments are received and if no objections are raised by either Congress or the Office of Management and Budget within 40 days of being notified of the proposed match, the computer matching program becomes effective and the respective agencies may begin the exchange at a mutually agreeable time and thereafter on a quarterly basis. By agreement between OPM and DMDC, the matching program will be in effect for 18 months with an option to renew for 12 additional months unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

G. *For Questions, Contact:* Acting Director, Defense Privacy and Civil Liberties Office, 241 18th Street South, Suite 101, Arlington, VA 22202. Telephone (703) 571–0070.

[FR Doc. 2014–02842 Filed 2–7–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Notice of Intent to Grant Exclusive Patent License; Harvest Optimization LLC

AGENCY: Office of the General Counsel, Department of Energy.

ACTION: Notice of intent to grant exclusive patent license.

SUMMARY: Notice is hereby given to an intent to grant to Harvest Optimization LLC of Rigby, Idaho, an exclusive license to practice the inventions described in U.S. Patent No. 7,311,013 entitled "Complex Pendulum Biomass Sensor" and U.S. Patent No. 8,469,784 entitled "Autonomous Grain Combine Control System." The inventions are owned by the United States of America, as represented by the U.S. Department of Energy (DOE).

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than February 25, 2014.

ADDRESSES: Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Michael Badagliacca, Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, Forrestal Building, Room 6F–067, 1000 Independence Ave. SW., Washington, DC 20585; Telephone (202) 586–4792.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 209 provides federal agencies with authority to grant exclusive licenses in federally-owned inventions, if, among other things, the agency finds that the public will be served by the granting of the license. The statute requires that no exclusive license may be granted unless public notice of the intent to grant the license has been provided, and the agency has considered all comments received in response to that public notice, before the end of the comment period.

Harvest Optimization LLC of Rigby, Idaho has applied for an exclusive

license to practice the inventions embodied in U.S. Patent Nos. 7,311,013 and 8,469,784 and has plans for commercialization of the inventions.

The exclusive license will be subject to a license and other rights retained by the U.S. Government, and other terms and conditions to be negotiated. DOE intends to negotiate to grant the license, unless, within 15 days of this notice, the Assistant General Counsel for Technology Transfer and Intellectual Property, Department of Energy, Washington, DC 20585, receives in writing any of the following, together with supporting documents:

(i) A statement from any person setting forth reason why it would not be in the best interests of the United States to grant the proposed license; or

(ii) An application for a nonexclusive license to the invention in which applicant states that if already has brought the invention to practical application or is likely to bring the invention to practical application expeditiously

The Department will review all timely written responses to this notice, and will proceed with negotiating the license if, after consideration of written responses to this notice, a finding is made that the license is in the public interest.

Issued in Washington, DC on February 4, 2014.

John T. Lucas,

Assistant General Counsel for Technology Transfer and Intellectual Property.

[FR Doc. 2014–02811 Filed 2–7–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Advanced Scientific Computing Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of Open Teleconference Meeting.

SUMMARY: This notice announces a meeting of the Advanced Scientific Computing Advisory Committee (ASCAC). Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, February 10, 2014, 11:00 a.m. to 12:30 p.m. ET.

ADDRESSES: The meeting is open to the public. To access the call:

1. Dial Toll-Free Number: 866–740–1260 (U.S. & Canada)

2. International participants dial: *http://www.readytalk.com/intl.*

3. Enter access code 8083012, followed by "#"

To ensure we have sufficient access lines for the public, we request that members of the public notify the DFO, Christine Chalk, that you intend to call-into the meeting via email at *christine.chalk@science.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Melea Baker, Office of Advanced Scientific Computing Research SC–21/ Germantown Building; U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–1290; Telephone (301)–903–7486, (Email: *Melea.Baker@science.doe.gov*).

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of this meeting is to provide advice and guidance on a continuing basis to the Department of Energy on scientific priorities within the field of advanced scientific computing research.

The notice of meeting is being published outside the normal minimum requirements due to inclement weather closings of the government in the Washington, DC, area., availability of members, and this meeting needs to be held prior to a related meeting previously-scheduled for February 11, 2014.

Agenda Topic

- Discussion on the exascale computing final report.

Public Participation: The teleconference meeting is open to the public.

If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Melea Baker via FAX at 301–903–4846 or via email (*Melea.Baker@science.doe.gov*). You must make your request for an oral statement prior to the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying by contacting Melea Baker at the address and/or email listed above.

Issued in Washington, DC on February 5, 2014.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2014–02904 Filed 2–7–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This notice is being issued under the authority of section 131.a. of the Atomic

Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Between the Government of the United States of America and the Government of Japan Concerning Peaceful Uses of Nuclear Energy and the Agreement for Cooperation Between the United States of America and the Republic of Kazakhstan Concerning Peaceful Uses of Nuclear Energy.

DATES: This subsequent arrangement will take effect no sooner than February 25, 2014.

FOR FURTHER INFORMATION CONTACT: Ms. Katie Strangis, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–8623 or email: *Katie.Strangis@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement is an amendment to the existing subsequent arrangement that was published in the **Federal Register** on June 13, 2012 (77 FR 35366) and went into effect in June 2012. The subsequent arrangement currently authorizes the retransfer of 6,672,212 g of U.S.-origin enriched uranium fuel fabrications scrap, containing 233,977 g of the isotope U–235 (less than five percent enrichment), from Nuclear Fuel Industries, Ltd. in Minato-Ku, Tokyo, Japan, to Ulba Metallurgical Plant in Ust-Kamengorsk, Kazakhstan. The purpose of the amendment is to increase the cumulative total authorized for retransfer to 6,734,183 g of U.S.-origin enriched uranium fuel fabrications scrap, containing 238,582 g of the isotope U–235 (less than five percent enrichment). Subject to the existing subsequent arrangement, Nuclear Fuel Industries, Ltd. has already shipped 2,910,869 g of the specified material to Ulba Metallurgical Plant. The remaining 3,823,314 g of enriched uranium, which is currently located at Nuclear Fuels Industries, Ltd. in Japan, will be transferred to Ulba Metallurgical Plant for the purpose of recovering uranium from fuel fabrication scrap for return to Japan where it will be fabricated into

fuel pellets to be used by Kansai Electric Power Co., in Osaka, Japan. The material was originally obtained by Nuclear Fuel Industries, Ltd. from nuclear fuel manufacturers in the United States pursuant to several Nuclear Regulatory Commission licenses.

In accordance with section 131a.of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security of the United States of America.

Dated: January 15, 2014.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2014–02814 Filed 2–7–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

External Merit Review Meeting

AGENCY: Wind and Water Power Technologies, Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of External Peer Review Meeting.

SUMMARY: The Water Power Program within the U.S. Department of Energy's (DOE) Office of Energy Efficiency and Renewable Energy intends to hold an External Merit Review in Arlington, VA, on February 24–28, 2014. The External Review Panel will review current projects and provide feedback on technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of projects. The review panel will also assess projects potential impact on the water power industry and identify additional research initiatives and resources that might be required in the future.

DATES: DOE will hold the External Peer Review from Monday, February 24th, through Friday, February 28, 2014.

ADDRESSES: The public meeting will be held at the DoubleTree Crystal City, 300 Army Navy Drive, Arlington, VA, 22203.

You may submit comments, identified by any of the following methods:

• Email: [*Mark.Higgins@ee.doe.gov*]. Include "Water Power Peer Review" in the subject line of the message.

• Postal Mail: [Mark Higgins, EE–4W, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585] Due to the potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages respondents to submit comments electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Stephanie Shuff, Energetics, Inc. 401 D Street SW. Suite 1000, Washington, DC 20024, *sshuff@energetics.com*

SUPPLEMENTARY INFORMATION:

Background

The U.S. Department of Energy's (DOE) Wind and Water Power Technologies is committed to developing and deploying a portfolio of innovative technologies for clean, domestic power generation from resources such as hydropower, waves, and tides. The Wind and Water Power Technologies portfolio is aimed at producing the next generation of water power technologies and jump-starting private sector innovation that is critical to the country's long-term economic growth, energy security, and international competitiveness. By executing objective, comprehensive Peer Reviews, the Wind and Water Power Technologies Office ensures that its portfolio of project addresses industry needs and impacts the long-term development and deployment of water power technologies in the United States.

Public Participation

The event is open to the public based upon space availability. DOE will also accept public comments as described in **ADDRESSES** for purposes of developing the Water Power Program portfolio, but will not respond individually to comments received.

Participants should limit information and comments to those based on personal experience, individual advice, information, or facts regarding this topic. It is not the object of this session to obtain any group position or consensus from the meeting participants. To most effectively use the limited time, please refrain from passing judgment on another participant's recommendations or advice, and instead, concentrate on your individual experiences.

Following the meeting, a summary will be compiled by DOE and posted for public comment. For those interested in providing additional public comment, the summary will be posted at *water.energy.gov.*

Information on Services for Individuals with Disabilities

Individuals requiring special accommodations at the meeting, please contact Mark Higgins no later than the close of business on February 24, 2014.

Issued in Washington, DC on February 3rd, 2014.

Jose Zayas,

Director, Wind and Water Power Technologies Office, U.S. Department of Energy.

[FR Doc. 2014–02813 Filed 2–7–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC14–6–000]

Commission Information Collection Activities (FERC–600); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A) (2006), (Pub. L. 104–13), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–600 (Rules of Practice and Procedure: Complaint Procedures).

DATES: Comments on the collection of information are due April 11, 2014.

ADDRESSES: You may submit comments (identified by Docket No. IC14–6–000) by either of the following methods:

• *eFiling at the Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp.*

• *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–600, Rules of Practice and Procedure: Complaint Procedures.

OMB Control No.: 1902–0180.

Type of Request: Three-year extension of the FERC–600 information collection requirements with no changes to the current reporting requirements.

Abstract: The information is used by the Commission to implement the statutory provisions of the Federal Power Act (FPA), 16 U.S.C. 791a–825r; the Natural Gas Act (NGA), 15 U.S.C. 717–717w; the Natural Gas Policy Act (NGPA), 15 U.S.C. 3301–3432; the Public Utility Regulatory Policies Act of 1978 (PURPA), 16 U.S.C. 2601–2645; the Interstate Commerce Act (ICA), 49 U.S.C. App. 1 *et. seq.;* the Outer Continental Shelf Lands Act, 43 U.S.C. 1301–1356; and the Energy Policy Act of 2005, (Pub. L. 109–58) 119 Stat. 594.

For the natural gas industry, section 14(a) of the NGA [1] provides that the Commission may permit any person to file with it a statement in writing, under oath or otherwise, as it shall determine, as to any or all facts and circumstances concerning a matter which may be the subject of an investigation.

For public utilities, section 307(a) of the FPA [2] provides that the Commission may permit any person to file with it a statement in writing, under oath or otherwise, as it shall determine, as to any or all facts and circumstances concerning a matter which may be the subject of an investigation.

Section 215(d)(5) of the FPA [3] provides that the Commission, upon its own motion or upon complaint, may order the Electric Reliability Organization to submit to the Commission a proposed reliability standard or a modification to a reliability standard that addresses a specific matter if the Commission considers such a new or modified reliability standard appropriate to carry out this section.

For hydropower projects, section 19 of the FPA [4] provides that, as a condition of a license, jurisdiction is conferred upon the Commission, upon complaint of any person aggrieved or upon its own initiative, to exercise such regulation and control over services, rates, and charges until such time as the State shall have provided a commission or other authority for such regulation and control.

For qualifying facilities, section 210(h)(2)(B) of PURPA [5] provides that any electric utility, qualifying cogenerator, or qualifying small power producer may petition the Commission to enforce the requirements of the Commission's PURPA regulations.

For oil pipelines, in Part 1 of the Interstate Commerce Act, sections 1, 6 and 15 (recodified by Pub. L. 95–473 and found as an appendix to Title 49 U.S.C.),[6] the Commission is authorized to investigate the rates charged by oil pipeline companies subject to its jurisdiction. If an oil rate has been filed and allowed by the Commission to go into effect without suspension and hearing, the Commission can investigate the effective rate on its own motion or by complaint filed with the Commission. Section 13 of the ICA [7] provides that any person can file a complaint complaining of anything done or omitted to be done by an oil pipeline.

In Order No. 602,[8] the Commission revised its regulations governing complaints filed with the Commission under the above statutes. Order No. 602 was designed to encourage and support consensual resolution of complaints, and to organize the complaint procedures so that all complaints are handled in a timely and fair manner. In order to achieve this result, the Commission revised Rule 206 of its Rules of Practice and Procedure (18 CFR 385.206) to require that a complaint satisfy certain informational requirements, to require that answers be filed in a shorter, 20-day time frame, and to provide that parties may employ various types of alternative dispute resolution procedures to resolve their disputes.

The data in complaints filed by interested/affected parties regarding jurisdictional oil, natural gas, electric and hydropower operations, facilities, and services are used by the Commission in establishing a basis to make an initial determination regarding the merits of the complaint and whether or not to undertake further investigation. Investigations may range from whether there is undue discrimination in rates or services to questions regarding market power of regulated entities to environmental concerns. In order to make an informed determination, it is important to know the specifics underlying any oil, gas, electric, and hydropower complaint "up-front" in a timely manner and in sufficient detail to allow the Commission to act swiftly. In addition, such complaint data helps the Commission and interested parties to monitor, e.g., the market for undue discrimination or exercises of market power. The information is voluntary but submitted pursuant to prescribed filing requirements. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR Parts 343 and 385.

Type of Respondents: Interested/affected parties regarding oil, natural gas, electric and hydropower operations, facilities, and services.

Estimate of Annual Burden:[9] The estimated annual burden and cost follow.

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response	Total annual burden hours & total annual cost	Average annual cost per respondent
	(1)	(2)	(1)*(2) = (3)	(4)	(5)	(6)
FERC–600	62	1	62	[10] 160 [11] $11,280	[12] 9,920 [13] $699,360	$11,280

[1] 15 U.S.C. 717m; *accord* 15 U.S.C. 717d.

[2] 16 U.S.C. 825f(a); *accord* 16 U.S.C. 824e.

[3] 16 U.S.C. 824o(d)(5).

[4] 16 U.S.C. 812.

[5] 16 U.S.C. 824a–3(h)(2)(B).

[6] 49 App. U.S.C. 1 *et seq* (1988).

[7] *Id. 13.*

[8] 64 FR 17087 (April 8, 1999).

[9] The Commission defines "burden" as the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

[10] We have re-evaluated the time and effort involved in preparing and filing a complaint, in light of the current complexities of the industries

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02738 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 5–094, 1869–056, 2188–216, and 2301–038]

PPL Montana, LLC; NorthWestern Corporation; Notice of Application for Transfer of Licenses and Soliciting Comments and Motions To Intervene

On January 10, 2014, PPL Montana, LLC (transferor) and NorthWestern Corporation (transferee) filed an application for transfer of licenses for the following projects.

Project number	Project name	Location
P–5–094	Kerr Project	Flathead River and Flathead Creek, Flathead Lake County, MT.
P–1869–056	Thompson Falls Project	Clark Fork Columbia River, Sanders County, MT.
P–2188–216	Missouri-Madison Project	Missouri and Madison Rivers, Cascade, Madison, Gallatin, Lewis, and Clark counties, MT.
P–2301–038	Mystic Lake Hydroelectric Project	West Rosebud Creek, Stillwater and Carbon counties, MT.

The transferor and transferee seek Commission approval to transfer the licenses for the above mentioned projects from the transferor to the transferee.

Applicant Contacts: For Transferor: Mr. David B. Kinnard, Associate General Counsel, PPL Montana LLC, 303 North Broadway, Suite 400, Billings, MT 59101, *Phone:* (406) 237–6903, *Email: dbkinnard@pplweb.com.* Mr. Jesse A. Dillon and Mr. Robert G. Grassi, PPL Services Corporation, Two North Ninth Street, Allentown, PA 18101, Phone: (610) 774–5013, *Fax:* (610) 774–6726, *Email: jadillon@pplweb.com.* Mr. David R. Poe, Bracewell & Giuliani LLP, 2000 K Street NW., Suite 500, Washington, DC 20006, *Phone:* (202) 828–5800, *Fax:* (800) 404–3970, *Email: david.poe@bgllp.com.* For Transferee: Mr. M. Andrew McLain, Corporate Counsel & FERC Compliance Officer, NorthWestern Energy, 208 N. Montana Ave., Suite 205, Helena, MT 59601, *Phone:* (406) 443–8987, *Email: andrew.mclain@northwestern.com.* Mr. William B. Conway Jr. and Gerald L. Richman, Skadden, Arps, Slate, Meagher & Flom LLP, 1440 New York Avenue NW., Washington, DC 20005, *Phone:* (202) 371–7135, *Fax:* (202) 661–0535, Emails: *william.conway@skadden.com* and *gerald.richman@skadden.com.*

FERC Contact: Patricia W. Gillis, (202) 502–8735.

Deadline for filing comments and motions to intervene: 30 days from the issuance date of this notice, by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–5–094, P–1869–056, P–2188–216, or P–2301–038.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02739 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. DI13–8–000]

Alaska Electric Light and Power Company; Notice of Declaration of Intention and Soliciting Comments, Protests, and/or Motions To Intervene

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Declaration of Intention.

b. *Docket No:* DI13–8–000.

c. *Date Filed:* June 12, 2013.

d. *Applicant:* Alaska Electric Light and Power Company.

e. *Name of Project:* Sheep Creek Hydroelectric Project.

f. *Location:* The proposed Sheep Creek Hydroelectric Project will be located on Sheep Creek, near the City and Borough of Juneau, Alaska, affecting T. 041S, R. 68E, Copper River Median and T. 042S, R. 68E, Copper River Median.

g. *Filed Pursuant to:* Section 23(b)(1) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Scott Willis, Vice President Generation, Alaska Electric Light and Power Company, 5601 Tonsgard Court, Juneau, AK

regulated by FERC. As a result, we think an estimate of 160 hours per complaint is a more realistic average of the burden per filing. The reporting requirements have not been revised.

[11] $70.50/hour is the average hourly cost of a FERC employee (salary plus benefits) for Fiscal Year 2014. We assume that the respondents to this collection are similarly situated in terms of salary plus benefits.

Average cost per response = Average burden hours per response [160 hours] * $70.50 per hour.

[12] Total annual burden hours = Total number of responses [62] * Average burden hours per response [160].

[13] Total annual cost = Total annual burden hours [9,920] * hourly cost [$70.50].

99801; Telephone: (907) 463–6396; Fax: (907) 463–4833; Email address: *Scott.Willis@aelp.commailto:mpdpe@aol.com.*

i. *FERC Contact:* Any questions on this notice should be addressed to Ashish Desai, (202) 502–8370, or Email address: *Ashish.Desai@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file any motion to intervene, protest, comments, and/or recommendations using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include the docket number (DI13–8–000). For more information on how to submit these types of filings, please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.*

Please include the docket number (DI13–8–000) on any comments, protests, and/or motions filed.

k. *Description of Project:* The Sheep Creek Hydroelectric Project will consist of: (1) A 10-foot-high, 75-foot-long concrete diversion dam at an elevation of 620 feet above mean sea level; (2) an overflow spillway; (3) a 4,750-foot-long, 36-inch-diameter penstock; (4) a powerhouse containing a single, 3.3-megawatt generating unit; (5) a tailrace that would discharge directly into Sheep Creek; (6) a switchyard, located adjacent to the powerhouse, consisting of a single 3.5-megavolt-ampere transformer to adjust voltage to 23 kilovolts; and (7) appurtenant facilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the project would affect the interests of interstate or foreign commerce. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's reservoir, head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the Docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOlineSupport@ferc.gov* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—All filings must bear in all capital letters the title "COMMENTS", "PROTESTS", AND/OR "MOTIONS TO INTERVENE", as applicable, and the Docket Number of the particular application to which the filing refers. A copy of any Motion to Intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02736 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice Of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC14–50–000.

Applicants: Northern States Power Company, a Minnesota corporation, Border Winds Energy, LLC, Pleasant Valley Wind, LLC.

Description: Authorization under Section 203 of the Federal Power Act.

Filed Date: 1/30/14.

Accession Number: 20140130–5367.

Comments Due: 5 p.m. ET 2/20/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2249–003.

Applicants: Portland General Electric Company.

Description: Notice of Non-Material Change in Status of Portland General Electric Company.

Filed Date: 1/30/14.

Accession Number: 20140130–5369.

Comments Due: 5 p.m. ET 2/20/14.

Docket Numbers: ER10–2881–011; ER10–2882–011; ER10–2883–011; ER10–2884–011; ER10–2885–011; ER10–2641–011; ER10–2663–011; ER10–2886–011; ER13–1101–006; ER13–1541–005.

Applicants: Alabama Power Company, Southern Power Company, Mississippi Power Company, Georgia Power Company, Gulf Power Company, Oleander Power Project, Limited Partnership, Southern Company—Florida LLC, Southern Turner Cimarron I, LLC, Spectrum Nevada Solar, LLC, Campo Verde Solar, LLC.

Description: Notification of Non-Material of Change in Status of Alabama Power Company, et. al.

Filed Date: 1/30/14.

Accession Number: 20140130–5386.

Comments Due: 5 p.m. ET 2/20/14.

Docket Numbers: ER14–1209–000.

Applicants: Southwest Power Pool, Inc.

Description: Attachment H and Attachment T Clean-Up Filing to be effective 1/1/2012.

Filed Date: 1/30/14.
Accession Number: 20140130–5178.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1210–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–01–30_SA 6502 Illinois Power-Edwards SSR Agreement to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5190.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1211–000.
Applicants: PacifiCorp.
Description: Salt River Project MOU ? First Revised to be effective 4/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5192.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1212–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–01–30_Schedule 43C Illinois Power Edwards SSR to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5198.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1213–000.
Applicants: Puget Sound Energy, Inc.
Description: The Boeing Company TX Agreements 676, 677 & 678 to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5200.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1214–000.
Applicants: Puget Sound Energy, Inc.
Description: Amcor Rigid Plastics USA, Inc. to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5258.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1215–000.
Applicants: Duke Energy Carolinas, LLC.
Description: DEC OATT SA Nos. 208, 406, 447 and 448 (2014) to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5262.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1216–000.
Applicants: California Independent System Operator Corporation.
Description: 2014–01–30_RevisionsToPriceCorrections to be effective 2/10/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5269.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1217–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwestern Power Administration Rate Change to be effective 10/1/2013.
Filed Date: 1/30/14.
Accession Number: 20140130–5271.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1218–000.
Applicants: Armstrong Energy Limited Partnership, L.L.L.P.
Description: Notice of Succession to be effective 1/31/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5333.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1219–000.
Applicants: Armstrong Energy Limited Partnership, L.L.L.P.
Description: Notice of Succession and Non-Material Change in Status to be effective 1/31/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5338.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1220–000.
Applicants: California Independent System Operator Corporation.
Description: 2014–01–30_RA_OneForMany to be effective 4/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5341.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1221–000.
Applicants: PJM Interconnection, L.L.C.
Description: ISAs for the Transfer Of Ohio Power Company's Generating Facilities to be effective 12/31/2013.
Filed Date: 1/30/14.
Accession Number: 20140130–5342.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1222–000.
Applicants: PJM Interconnection, L.L.C.
Description: First Revised Service Agreement No. 3195; Queue Position W1–113/W2–078 to be effective 12/31/2013.
Filed Date: 1/30/14.
Accession Number: 20140130–5345.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1223–000.
Applicants: Pure Energy USA LLC.
Description: MBR Application to be effective 3/31/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5347.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1224–000.
Applicants: Duke Energy Carolinas, LLC.
Description: PMPA NITSA revisions OATT SA 355 to be effective 1/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5352.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1225–000.
Applicants: Southwest Power Pool, Inc.
Description: Implement Lea County Stated Rate to be effective 4/1/2014.
Filed Date: 1/30/14.
Accession Number: 20140130–5359.
Comments Due: 5 p.m. ET 2/20/14.
Docket Numbers: ER14–1226–000.
Applicants: Portland General Electric Company.
Description: Order 784 Compliance Filing for MBR to be effective 1/31/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5000.
Comments Due: 5 p.m. ET 2/21/14.
Docket Numbers: ER14–1227–000.
Applicants: Verus Energy Trading, LLC.
Description: Notice of Cancellation of MBR Tariff to be effective 2/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5049.
Comments Due: 5 p.m. ET 2/21/14.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH14–5–000.
Applicants: LS Power Development, LLC.
Description: FERC 65–B Waiver Notification.
Filed Date: 1/30/14.
Accession Number: 20140130–5392.
Comments Due: 5 p.m. ET 2/20/14.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 31, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–02679 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1401–001.
Applicants: Southwest Power Pool, Inc.
Description: Motion to Withdraw Rate Schedule No. 11 in ER12–1401 to be effective 12/19/2013.
Filed Date: 1/31/14.
Accession Number: 20140131–5416.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER12–1779–001.
Applicants: Southwest Power Pool, Inc.
Description: Motion to Withdraw Rate Schedule No. 11 in ER12–1779 to be effective 12/19/2013.
Filed Date: 1/31/14.
Accession Number: 20140131–5438.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER13–1697–000.
Applicants: Kiwi Energy Inc.
Description: Refund Report to be effective N/A.
Filed Date: 1/31/14.
Accession Number: 20140131–5501.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1212–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–01–31_Schedule 43C Illinois Power Edwards SSR Amendment to be effective 1/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5239.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1225–001.
Applicants: Southwest Power Pool, Inc.
Description: Lea County Stated Rate Amendment Filing to be effective 4/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5486.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1239–000.
Applicants: San Diego Gas & Electric Company.
Description: SDGE TO4 Formula Settlement Filing to be effective 9/1/2013.
Filed Date: 1/31/14.
Accession Number: 20140131–5487.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1240–000.
Applicants: Southwest Power Pool, Inc.
Description: 1276R6 KCP&L NITSA NOA to be effective 1/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5490.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1241–000.
Applicants: Southwest Power Pool, Inc.
Description: 2028R6 Sunflower Electric Power Corporation NITSA NOA to be effective 1/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5495.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1242–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–01–31_SA 6506 Presque Isle SSR Agreement to be effective 2/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5503.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1243–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–01–31_Schedule 43G Presque Isle SSR to be effective 2/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5506.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1244–000.
Applicants: New England Power Pool Participants Committee.
Description: February 2014 Membership Filing to be effective 1/1/2014.
Filed Date: 1/31/14.
Accession Number: 20140131–5508.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1245–000.
Applicants: FirstEnergy Solutions Corp.
Description: Application of FirstEnergy Solutions Corp. for authorization to sell electricity to The Potomac Edison Company, an affiliate.
Filed Date: 1/31/14.
Accession Number: 20140131–5537.
Comments Due: 5 p.m. e.t. 2/21/14.

Docket Numbers: ER14–1246–000.
Applicants: MATL LLP.
Description: Revise Schedule 7 for Auction to be effective 4/4/2014.
Filed Date: 2/3/14.
Accession Number: 20140203–5139.
Comments Due: 5 p.m. e.t. 2/24/14.

Docket Numbers: ER14–1247–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–02–03_SGIP Order 792 Compliance Filing to be effective N/A.
Filed Date: 2/3/14.
Accession Number: 20140203–5153.
Comments Due: 5 p.m. e.t. 2/24/14

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 3, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–02819 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER14–1040–000]

Lumens Energy Supply LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Lumens Energy Supply LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is February 24, 2014.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic

service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02737 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD13–12–000]

Joint Petition of the North American Electric, Reliability Corporation, and Texas Reliability Entity, Inc. for Approval of Proposed Regional Reliability Standard BAL–001–TRE–01—Primary Frequency Response in the ERCOT Region

In Reply Refer To: North American Electric, Reliability Corporation, Docket No. RD13–12–000.

Holly A. Hawkins, Assistant General Counsel, North American Electric Reliability Corporation, 1325 G Street, NW., Suite 600, Washington, DC 20005.

Tammy Cooper, General Counsel, Texas Reliability Entity, Inc., 805 Las Cimas Parkway, Suite 200, Austin, Texas 78746.

Reference: Joint Petition of the North American Electric Reliability Corporation and Texas Reliability Entity, Inc. for approval of proposed regional Reliability Standard BAL–001–TRE–01—Primary Frequency Response in the ERCOT region.

Dear Mmes. Hawkins and Cooper:

1. On September 18, 2013, the North American Electric Reliability Corporation (NERC) and the Texas Reliability Entity, Inc. (Texas RE) filed a joint petition (Petition) seeking approval of proposed regional Reliability Standard BAL–001–TRE–01 (Primary Frequency Response), implementation plan, and the associated violation risk factors and

1. violation severity levels in response to the Order No. 693 directive to develop a regional Reliability Standard for assuring frequency performance in the ERCOT Interconnection.[1]

2. 2. The Petition states that the purpose of proposed regional Reliability Standard BAL–001–TRE–01 is to maintain ERCOT Interconnection steady-state frequency within defined limits by balancing real-power demand and supply in real-time. This reliability goal is accomplished by requiring prompt and sufficient frequency response from resources to stabilize frequency during changes in the system generation-demand balance.[2] Pursuant to section 215(d) of the Federal Power Act, we approve regional Reliability Standard BAL–001–TRE–01 as just, reasonable, not unduly discriminatory or preferential, and in the public interest.

3. On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards and associated definitions filed by NERC, including Reliability Standard BAL–001–0.[3] In Order No. 693, the Commission approved a regional difference for the ERCOT Interconnection from Reliability Standard BAL–001–0, allowing ERCOT to be exempt from Requirement R2. In doing so, the Commission found that ERCOT's approach to frequency response under its own protocols appeared to be more stringent than Requirement R2. As with other new regional Reliability Standards, the Commission stated that it "expects that the ERCOT regional difference will include Requirements, Measures and Levels of Non-Compliance sections."[4]

4. On September 18, 2013, NERC and the Texas RE filed a joint petition (Petition) seeking approval of regional Reliability Standard BAL–001–TRE–01 (Primary Frequency Response), implementation plan, and the associated violation risk factors and violation severity levels. The Petition states that regional Reliability Standard BAL–001–TRE–01 complies with the Commission's directive in Order No. 693. The Petition further states that, while the regional Reliability Standard requires individual generators to provide frequency response, it does not restrict the balancing authority from obtaining frequency response from other sources to meet the Interconnection's required level of performance.[5]

5. NERC states that the regional Reliability Standard was developed and approved by industry stakeholders using the Texas RE *Texas Reliability Entity Standards Development Process,* approved by the Texas RE Board of Directors on April 23, 2013, and subsequently approved by the NERC Board of Trustees on August 15, 2013. NERC states that the proposed regional Reliability Standard is applicable to balancing authorities, generator owners, and generator operators within the footprint of the Texas RE in the ERCOT Interconnection.

6. NERC asserts that regional Reliability Standard BAL–001–TRE–01 improves upon ERCOT's existing practices for frequency response, is necessitated by physical differences in the ERCOT system and represents an alternative, more stringent means of ensuring frequency response performance than the continent-wide NERC Reliability Standard.[6]

7. Regional Reliability Standard BAL–001–TRE–01 has ten requirements related to: (1) identifying and posting frequency measureable events (Requirement R1); (2) calculating the primary frequency response of each resource in the Interconnection (Requirement R2); (3) calculating the Interconnection minimum frequency response and monitoring the actual frequency response of the Interconnection (Requirements R3–R5); (4) requiring resources to operate in accordance with specified governor deadband and droop parameters and to promptly notify the balancing authority of any change in governor status (Requirements R6–R8); and (5) providing primary frequency response performance requirements for each generator (Requirements R9–R10). The requirements in BAL–001–TRE–01 work together to help ensure that generation and load remain balanced—or are quickly restored to balance—in the

[1] *Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, 72 FR 16416 (Apr. 4, 2007), FERC Stats. & Regs. ¶ 31,242, at PP 313–15 (2007), *order on reh'g,* Order No. 693–A, 120 FERC ¶ 61,053 (2007).

[2] Petition at 10.

[3] Order No. 693, FERC Stats. & Regs. ¶ 31,242 at PP 313–315.

[4] *Id.* P 315.

[5] Petition at 11.

[6] *Id.* at 3.

ERCOT Interconnection so that system frequency is restored to stability and near normal frequency even after a significant event occurs on the system.

8. NERC also seeks approval of the implementation plan for BAL–001–TRE–01, as follows. On the first day of the first calendar quarter that is 12 months following the effective date of BAL–001–TRE–01, the balancing authority, *i.e.*, ERCOT, and generator operators must be fully compliant with Requirements R1and R8, respectively. Further, the implementation plan mandates that at least 50 percent of each generator owner's generating units/generating facilities must be compliant with Requirements R6 and R7 the first calendar quarter that is 12 months following the effective date of BAL–001-TRE–01. The balancing authority must become fully compliant with Requirements R2, R3, R4 and R5 the first calendar quarter that is 18 months following the effective date of BAL–001–TRE–01, and 100 percent of the generator owner's generating units/generating facilities must be compliant with Requirement R7 within this same time period. Compliance with Requirements R9 and R10 on at least 50 percent of the generator owner's generating units/generating facilities is required the first calendar quarter that is 24 months following the effective date of BAL–001–TRE–01. Similarly, 100 percent of the generator owner's units/generating facilities are required to be compliant with Requirements R9 and R10 the first calendar quarter that is 30 months following the effective date of BAL–001–TRE–01.

9. NERC's filing was noticed on September 23, 2013, with comments, interventions and protests due on or before October 15, 2013. No comments or protests were filed.

10. We approve regional Reliability Standard BAL–001–TRE–01 and the associated implementation plan, violation severity levels and violation risk factors. We find that the regional Reliability Standard is just, reasonable, not unduly discriminatory or preferential, and in the public interest. Reliability Standard BAL–001–TRE–01 is a comprehensive frequency response standard that adequately addresses all applicable Commission directives and we believe it will protect and improve reliability in the ERCOT Interconnection by enabling entities to maintain sufficient frequency response that can be made quickly available to arrest possible frequency excursions. We concurrently have approved Reliability Standard BAL–003–1, which addresses frequency response on a continent-wide basis. [7] As noted in the approval of BAL–003–1, the method of obtaining frequency response in BAL–001–TRE–01 may provide balancing authorities the means to procure sufficient resources to satisfy their frequency response obligations if such challenges should occur. [8] These are new Reliability Standards both nationally and for the ERCOT Interconnection. As with the national standard, because no regional standard existed previously, Reliability Standard BAL–001–TRE–01 represents a step forward in improving reliability of the Bulk-Power System in the ERCOT Interconnection.

11. The Commission also finds that NERC's proposed violation risk factors and violation severity levels for regional Reliability Standard BAL–001–TRE–01 are consistent with the Commission's established guidelines for review of proposed violation risk factors and violation severity levels, and find NERC's proposed implementation plan reasonable. Accordingly, we approve NERC's proposed violation risk factors, violation severity levels and implementation plan for Reliability Standard BAL–001–TRE–01.

Information Collection

12. The Office of Management and Budget (OMB) regulations require approval of certain information collection requirements imposed by agency actions.[9] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirement of this order will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission will submit these reporting and record keeping requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.

13. This order is effective immediately; however, the revised information collection requirements will not be effective or enforceable until OMB approves the information collection changes described in this order. Comments are solicited within 60 days of the date this order is published in the **Federal Register** on the Commission's need for this information, whether the information will have practical utility, the accuracy of provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing the respondent's burden, including the use of automated information techniques. Submit comments following the Commission's submission guidelines at *http://www.ferc.gov/help/submission-guide.asp* and reference Docket No. RD13–12.

14. Regional Reliability Standard BAL–001–TRE–01 is more comprehensive than the existing continent-wide Reliability Standards addressing frequency response, BAL–001–0.1a and BAL–003–0.1b in that the regional standard includes additional requirements and applies to generator owners and generator operators as well as balancing authorities. The expanded applicability of the regional Reliability Standard, thus, increases the reporting burden for entities that operate within the ERCOT Interconnection.

15. *Burden Estimate:* Our estimate below regarding the number of respondents is based on the NERC compliance registry as of October 2013. According to the registry, the ERCOT region includes 40 generator owners, 14 generator operators, 75 generator owners that are also generator operators, and one balancing authority. Thus, we estimate that a total of 130 entities are potentially subject to the reporting requirements of BAL–001–TRE–01.

16. The information collection requirements the setting or configuration of the Control System software, identification and recording of events, data retention and submitting a report as outlined in the table below.

[7] *See Frequency Response and Frequency Response Bias Setting Reliability Standard,* Order No. 794, 146 FERC ¶ 61,024.

[8] *Id.*

[9] 5 CFR 1320.10.

FERC–725T	Number of respondents [10] (1)	Number of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1) x (2) x (3)	Total annual cost [11]
Maintain and submit Event Log Data	.....	1			$960
	BA	1	16	16	($60/hr.)
Modification to Governor Controller Setting/Configuration ..	114				$75,440
	GO	1	8	920	One-time ($82/hr.)
Evidence Retention	130				$8,320
	BA/GO/GOP	1	2	260	($32/hr.)
TOTAL				1,196	$84,720

Title: Mandatory Reliability Standards for the Bulk-Power System

Action: Proposed revisions to FERC–725T.

OMB Control No: To Be Determined

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: Modification to Governor Controller; once in the life of the equipment. Maintaining and Submitting Log Data; annually

Necessity of the Information: Reliability Standard BAL–001–TRE–01 satisfies certain prior directives of the Commission that include requirements concerning frequency response.

Interested persons may obtain information on the reporting requirements by contacting: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* Phone: (202) 502–8663, fax: (202) 273–0873].

By the direction of the Commission.

Dated: January 16, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–01217 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD14–13–000]

North Wales Water Authority; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On January 27, 2014, the North Wales Water Authority filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act, as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The Meetinghouse Road Water Transfer NO 3 Station 29 In-Pipe Hydropower Project would utilize an existing pipe paralleling the pressure reducing valve within Station 29 of North Wales Water Authority's water distribution system in Montgomery County, Pennsylvania.

Applicant Contact: Frank Zammataro, Rentricity Inc., P.O. Box 1021, Planetarium Station, New York, NY 10024, Phone No. (732) 319–4501.

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) The existing Station 29 building; (2) one proposed 11-kilowatt turbine/generating unit to be place on an existing 12-inch bypass line; and (3) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 72 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	*Description*	*Satisfies (Y/N)*
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

[10] BA = Balancing Authority, GO = Generator Owner, GOP = Generator Operator.

[11] The estimates for cost per hour (rounded to the nearest dollar) are derived as follows:

- $60/hour, the average salary plus benefits per engineer (from Bureau of Labor Statistics at *http://bls.gov/oes/current/naics3_221000.htm).*
- $82/hour, the salary plus benefits per manager (from Bureau of Labor Statistics at *http://bls.gov/oes/current/naics3_221000.htm).*
- $32/hour, the salary plus benefits per information and record clerks (from Bureau of Labor Statistics at *http://bls.gov/oes/current/naics3_221000.htm).*

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the "COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY" or "MOTION TO INTERVENE," as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov*, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the "eLibrary" link. Enter the docket number (e.g., CD14–13) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02735 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2013).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14568–000]

CB Energy Park, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Competing Applications

On December 2, 2013, CB Energy Park, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Coffin Butte Pumped Storage Hydro Project (Coffin Butte Project) to be located near Two Dot in Wheatland County, Montana. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following:

Lower Reservoir

(1) A 5,000-foot-long, 50-foot-high earth and roller compacted concrete embankment; (2) a 50-acre lower reservoir with a storage capacity of 2,500-acre-foot at an elevation of 5,200 feet; (3) a temporary diversion with a pump and pipeline to bring initial fill water to the lower reservoir from Miller Creek; (4) a well to bring groundwater to the project to make up evaporation and seepage losses; (5) a powerhouse containing two reversible 125-megawatt (MW) turbine/generator units, for a total installed capacity of 250 MW; and (6) an approximately 2-mile-long, 230-kilovolt (kV) transmission line connecting to an existing 500-kV transmission line in the area or a 7-mile-long, 230-kV transmission line connecting to the existing Two Dot substation.

Upper Reservoir

(1) A 4,600-foot-long, 50-foot-high earth and roller compacted concrete embankment; (2) a 50-acre upper reservoir with a storage capacity of 2,500-acre-foot at an elevation of 6,240 feet; (3) a 18-foot-diameter, 5,000-foot-long steel-lined tunnel extending to the powerhouse; and (4) appurtenant facilities.

The estimated annual generation of the Coffin Butte Project would be 880,000 megawatt-hours.

Applicant Contact: Carl Borgquist, CB Energy Park, LLC, P.O. Box 309, Bozeman, MT 59771; phone: (406) 585–3006; or Martin J. Weber, P.E., Stanley Consultants, Inc., 5775 Wayzata Blvd., No. 300, Minneapolis, MN 55416; phone: (952) 546–3669.

FERC Contact: Dianne Rodman, (202) 502–6077.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/*

elibrary.asp. Enter the docket number (P–14568–000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02743 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7684–001]

Sharon and Marcia Leishman; Notice of Termination of Exemption by Implied Surrender and Soliciting Comments and Protests

Take notice that the following hydroelectric proceeding has been initiated by the Commission:

a. *Type of Proceeding:* Termination of exemption by implied surrender

b. *Project No.:* 7684–001

c. *Date Initiated:* February 3, 2014

d. *Exemptee:* Sharon and Marcia Leishman

e. *Name and Location of Project:* The Leishman Irrigation System Project is located on the irrigation tailwater collection system on the Leishman's property in Kittitas County, Washington.

f. *Filed Pursuant to:* 18 CFR 4.106

g. *Exemptee Contact Information:* Sharon Leishman (425) 235–8118

h. *FERC Contact:* Krista Sakallaris, (202) 502–6302, *Krista.Sakallaris@ferc.gov*.

i. Deadline for filing comments and protests is 30 days from the issuance of this notice by the Commission. Please file your submittal electronically via the Internet (eFiling) in lieu of paper. Please refer to the instructions on the Commission's Web site under *http://www.ferc.gov/docs-filing/efiling.asp* and filing instructions in the Commission's Regulations at 18 CFR section 385.2001(a)(1)(iii). To assist you with eFilings you should refer to the submission guidelines document at *http://www.ferc.gov/help/submission-guide/user-guide.pdf*. In addition, certain filing requirements have statutory or regulatory formatting and other instructions. You should refer to a list of these "qualified documents" at *http://www.ferc.gov/docs-filing/efiling/filing.pdf*. You must include your name and contact information at the end of your comments. Please include the project number (P–7684–001) on any documents or motions filed. The Commission strongly encourages electronic filings; otherwise, you should submit an original and seven copies of any submittal to the following address: The Secretary, Federal Energy Regulatory Commission, Mail Code: DHAC, PJ–12, 888 First Street NE., Washington, DC 20426.

j. *Description of Project Facilities:* (1) A 1,100-foot-long, 12-inch-diameter PVC pipeline; (2) a powerhouse containing two generating units with rated capacities of 25 kW and 7.5 kW and a combined annual energy production of 60 MWh; and (3) a discharge conduit.

k. *Description of Proceeding:* The exemptee is in violation of Standard Article 1 of its exemption, which was granted April 6, 1984 (27 FERC ¶61,074). The Commission's regulation, 18 CFR 4.106, provides, among other things, that the Commission reserves the right to revoke an exemption if any term or condition of the exemption is violated.

Commission records indicate that the project stopped operating sometime between 1996 and 1999. After several years of correspondence regarding restoring operation to the project or surrounding the exemption, the exemptee has become non-responsive. On December 16, 2013, the Commission sent a letter indicating that the exemptee must file a plan and schedule to restore operation or surrender the project, failure to do so would result in an implied surrender. To date, the exemptee has not filed a response and the project remains inoperable.

l. This notice is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the Docket number (P–7684–001) excluding the last three digits in the docket number field to access the notice. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments and Protests*—Anyone may submit comments or protests in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.211. In determining the appropriate action to take, the Commission will consider all protests filed. Any protests must be received on or before the specified deadline date for the particular proceeding.

o. *Filing and Service of Responsive Documents*—Any filing must (1) bear in all capital letters the title "COMMENTS or "PROTEST," as applicable; (2) set forth in the heading the project number of the proceeding to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting or protesting; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments or protests should relate to project works which are the subject of the termination of exemption. A copy of any protest must be served upon each representative of the exemptee specified in item g above. A copy of all other filings in reference to this notice must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described proceeding. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

Dated: February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02742 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4609–007]

New Hampshire Wood Products Company Bath Electric Power Company LLC; Notice of Transfer of Exemption

1. By letter filed November 26, 2013, Bath Electric Power Company LLC parent company of New Hampshire Wood Products Company informed the Commission that the exemption from licensing for the Ammonoosuc River Dam Project, FERC No. 4609, originally issued January 11, 1982,[1] has been

[1] 18 FERC ¶ 62,026, Notice of Approval by Operation of Law.

transferred to Bath Electric Power Company LLC. The project is located on the Ammonoosuc River in Grafton County, New Hampshire. The transfer of an exemption does not require Commission approval.

2. Bath Electric Power Company LLC is now the exemptee of the Ammonoosuc River Dam Project, FERC No. 4609. All correspondence should be forwarded to: Bath Electric Power Company LLC, 112 Terrace Drive, North Haverhill, NH 03774.

Dated: Issued February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02741 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4542–014]

Bacon Felt Company, Inc., Salmon Falls Power & Light Company, LLC; Notice of Transfer of Exemption

1. By letter filed August 12, 2013, Bacon Felt Company, Inc. informed the Commission that the exemption from licensing for the Boston Felt Project, FERC No. 4542, originally issued August 29, 1983,[1] has been transferred to Salmon Falls Power & Light Company, LLC. The project is located on the Salmon Falls River in Strafford County, New Hampshire. The transfer of an exemption does not require Commission approval.

2. Salmon Falls Power & Light Company, LLC, located at P.O. Box 9, South Casco, ME 04077, is now the exemptee of the Boston Felt Project, FERC No. 4542.

Dated: Issued February 3, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–02740 Filed 2–7–14; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0021; FRL–9906–39–OECA]

Inquiry To Learn Whether Businesses Assert Business

Confidentiality Claims Regarding Waste Import and Export

[1] 24 FERC ¶ 62,240, Order Granting Exemption From Licensing of A Small Project of 5 Megawatts or Less.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for comment.

SUMMARY: The Environmental Protection Agency (EPA) receives from time to time Freedom of Information Act (FOIA) requests for documentation received or issued by EPA or data contained in EPA database systems pertaining to the export and import of Resource Conservation and Recovery Act (RCRA) hazardous waste from/to the United States, the export of cathode ray tubes (CRTs) and spent lead acid batteries (SLABs) from the United States, and the export and import of RCRA universal waste from/to the United States. These documents and data may identify or reference multiple parties, and describe transactions involving the movement of specified materials in which the parties propose to participate or have participated. The purpose of this notice is to inform "affected businesses" about the documents or data sought by these types of FOIA requests in order to provide the businesses with the opportunity to assert claims that any of the information sought that pertains to them is entitled to treatment as confidential business information (CBI), and to send comments to EPA supporting their claims for such treatment. Certain businesses, however, do not meet the definition of "affected business," and are not covered by today's notice. They consist of any business that actually submitted to EPA any document at issue pursuant to applicable RCRA regulatory requirements and did not assert a CBI claim as to information that pertains to that business in connection with the document at the time of its submission; they have waived their right to do so at a later time. Nevertheless, other businesses identified or referenced in the documents that were submitted to EPA by the submitting business may have a right to assert a CBI claim concerning information that pertains to them and may do so in response to this notice.

DATES: Comments must be received on or before March 12, 2014. The period for submission of comments may be extended if, before the comments are due, you make a request for an extension of the comment period and it is approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under the FOIA is pending.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2014–0021, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: kreisler.eva@epa.gov.*
- *Address:* Eva Kreisler, International Compliance Assurance Division, Office of Federal Activities, Office of Enforcement and Compliance Assurance, Environmental Protection Agency, Mailcode: 2254A, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2014–0021. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. Instructions about how to submit comments claimed as CBI are given later in this notice.

The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Please include your name and other contact information with any disk or CD–ROM you submit by mail. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is

not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the HQ EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the docket for this notice is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Eva Kreisler, International Compliance Assurance Division, Office of Federal Activities, Office of Enforcement and Compliance Assurance, Environmental Protection Agency, Mailcode: 2254A, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–8186; email address: *kreisler.eva@epa.gov*.

SUPPLEMENTARY INFORMATION: Today's notice relates to any documents or data in the following areas: (1) export of Resource Conservation and Recovery Act (RCRA) hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subparts E and H; (2) import of RCRA hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subparts F and H; (3) transit of RCRA hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subpart H, through the United States and foreign countries; (4) export of cathode ray tubes, during calendar year 2013 or before, under 40 CFR part 261, subpart E; (5) exports of non-crushed spent lead acid batteries with intact casings, during calendar year 2013 or before, under 40 CFR part 266 subpart G; (6) export and import of RCRA universal waste, during calendar year 2013 or before, under 40 CFR part 273, subparts B, C, D, and F;(7) submissions from transporters, during calendar year 2013 or before, under 40 CFR part 263, or from treatment, storage or disposal facilities under 40 CFR parts 264 and 265, related to exports or imports of hazardous waste which occurred during calendar year 2013 or before, including receiving facility notices under 40 CFR 264.12(a)(1) and 265.12(a)(1) and import consent documentation under 40 CFR 264.71(a)3) and 265.71(a)(3).

I. General Information

EPA has previously published notices similar to this one in the **Federal Register**, the latest one being at 77 FR 25475, January 14, 2013 that address issues similar to those raised by today's notice. The Agency did not receive any comments on the previous notices. Since the publication of the January 14, 2013 notice, the Agency has continued to receive FOIA requests for documents and data contained in EPA's database related to hazardous waste exports and imports.

II. Issues Covered by This Notice

Specifically, EPA receives FOIA requests from time to time for documentation or data related to hazardous waste exports and imports that may identify or reference multiple parties, and that describe transactions involving the movement of specified materials in which the parties propose to participate or have participated. This notice informs "affected businesses," [1] which could include, among others, "transporters" [2] and "consignees," [3] of the requests for information in EPA database systems and/or contained in one or more of the following documents: (1) documents related to the export of Resource Conservation and Recovery Act (RCRA) hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subparts E and H, including but not limited to the "notification of intent to export," [4]" manifests," [5] "annual reports," [6] "EPA acknowledgements of consent, [7] " " any subsequent communication withdrawing a prior consent or objection," [8] "responses that neither consent nor object," "exception reports," [9] "transit notifications," [10] and "renotifications;" [11] (2) documents related to the import of hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subparts F and H, including but not limited to notifications of intent to import hazardous waste into the U.S. from foreign countries; (3) documents related to the transit of hazardous waste, during calendar year 2013 or before, under 40 CFR part 262, subpart H, including notifications from U.S. exporters of intent to transit through foreign countries, or notifications from foreign countries of intent to transit through the U.S.; (4) documents related to the export of cathode ray tubes (CRTs), during calendar year 2013 or before, under 40 CFR part 261, subpart E, including but not limited to notifications of intent to export CRTs; (5) documents related to the export of non-crushed spent lead acid batteries (SLABs) with intact casings, during calendar year 2013 or before, under 40 CFR part 266 subpart G, including but not limited to notifications of intent to export SLABs; (6) submissions from transporters under 40 CFR part 263, or from treatment, storage or disposal facilities under 40 CFR parts 264 and 265, related to exports or imports of hazardous waste which occurred during calendar year 2013 or before, including receiving facility notices under 40 CFR 264.12(a)(1) and 265.12(a)(1) and import consent documentation under 40 CFR 264.71(a)(3) and 265.71(a)(3),and (7) documents related to the export and import of RCRA "universal waste" [12] under 40 CFR part 273, subparts B, C, D, and F.

Certain businesses, however, do not meet the definition of "affected business," and are not covered by today's notice. They consist of any business that actually submitted information responsive to a FOIA request, under the authority of 40 CFR parts 260 through 266 and 268, and did not assert a claim of business confidentiality covering any of that information at the time of submission. As set forth in the RCRA regulations at 40 CFR 260.2(b), "if no such [business confidentiality] claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the person submitting it." Thus, for purposes of this notice and as a general matter under 40 CFR 260.2(b), a business that submitted to EPA the documents at issue, pursuant to applicable regulatory requirements, and that failed to assert a claim as to information that pertains to it at the time of submission, cannot later

[1] The term "affected business" is defined at 40 CFR 2.201(d), and is set forth in this notice, below.

[2] The term "transporter" is defined at 40 CFR 260.10.

[3] The term "consignee" is defined, for different purposes, at 40 CFR 262.51 and 262.81(c).

[4] The term "notification of intent to export" is described at 40 CFR 262.53.

[5] The term "manifest" is defined at 40 CFR 260.10.

[6] The term "annual reports" is described at 40 CFR 262.56.

[7] The term "EPA acknowledgement of consent" is defined at 40 CFR 262.51.

[8] The requirement to forward to the exporter "any subsequent communication withdrawing a prior consent or objection" is found at 42 U.S.C. § 6938(e)

[9] The term "exception reports" is described at 40 CFR 262.55.

[10] The term "transit notifications" is described at 40 CFR 262.53(e).

[11] The term "renotifications" is described at 40 CFR 262.53(c).

[12] The term "universal waste" is defined at 40 CFR 273.9.

make a business confidentiality claim.[13] Nevertheless, other businesses identified or referenced in the same documents that were submitted to EPA by the submitting business may have a right to assert a CBI claim concerning information that pertains to them and may do so in response to this notice.

In addition, EPA may develop its own documents and organize into its database systems information that was originally contained in documents from submitting businesses relating to exports and imports of hazardous waste. If a submitting business fails to assert a CBI claim for the documents it submits to EPA at the time of submission, not only does it waive its right to claim CBI for those documents, but it also waives its right to claim CBI for information in EPA's documents or databases that is based on or derived from the documents that were originally submitted by that business.[14]

In accordance with 40 CFR 2.204(c) and (e), this notice inquires whether any affected business asserts a claim that any of the requested information constitutes CBI, and affords such business an opportunity to comment to EPA on the issue. This notice also informs affected businesses that, if a claim is made, EPA would determine under 40 CFR part 2, subpart B, whether any of the requested information is entitled to business confidential treatment.

1. Affected Businesses

EPA's FOIA regulations at 40 CFR 2.204(c)(1) require an EPA office that is responsible for responding to a FOIA request for the release of business information ("EPA office") "to determine which businesses, if any, are affected businesses * * *." "Affected business" is defined at 40 CFR 2.201(d) as, "* * * with reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed."

[13] However, businesses having submitted information to EPA relating to the export and import of RCRA universal waste are not subject to 40 CFR 260.2(b) since they submitted information in accordance with 40 CFR part 273, and not parts 260 through 266 and 268, as set forth in 40 CFR 260.2(b). They are therefore affected businesses that could make a claim of CBI at the time of submission or in response to this notice.

[14] With the exception, noted above, of the submission of information relating to the export and import of RCRA universal waste.

2. The Purposes of This Notice

This notice encompasses two distinct steps in the process of communication with affected businesses prior to EPA's making a final determination concerning the business confidentiality of the information at issue: the preliminary inquiry and the notice of opportunity to comment.

a. Inquiry To Learn Whether Affected Businesses (Other Than Those Businesses That Previously Asserted a CBI Claim) Assert Claims Covering Any of the Requested Information

Section 2.204(c)(2)(i) provides, in relevant part:

If the examination conducted under paragraph (c)(1) of this section discloses the existence of any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information.

b. Notice of Opportunity To Submit Comments

Sections 2.204(d)(1)(i) and 2.204(e)(1) of Title 40 of the Code of Federal Regulations require that written notice be provided to businesses that have made claims of business confidentiality for any of the information at issue, stating that EPA is determining under 40 CFR part 2, subpart B, whether the information is entitled to business confidential treatment, and affording each business an opportunity to comment as to the reasons why it believes that the information deserves business confidential treatment.

3. The Use of Publication in the Federal Register

Section 2.204(e)(1) of Title 40 of the Code of Federal Regulations requires that this type of notice be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt. EPA, however, has determined that in the present circumstances the use of a **Federal Register** notice is a practical and efficient way to contact affected businesses and to furnish the notice of opportunity to submit comments. The Agency's decision to follow this course was made in recognition of the administrative difficulty and impracticality of directly contacting potentially thousands of individual businesses.

4. Submission of Your Response in the English Language

All responses to this notice must be in the English language.

5. The Effect of Failure To Respond to This Notice

In accordance with 40 CFR 2.204(e)(1) and 2.205(d)(1), EPA will construe your failure to furnish timely comments in response to this notice as a waiver of your business's claim(s) of business confidentiality for any information in the types of documents identified in this notice.

6. What To Include in Your Comments

If you believe that any of the information contained in the types of documents which are described in this notice and which are currently, or may become, subject to FOIA requests, is entitled to business confidential treatment, please specify which portions of the information you consider business confidential. Information not specifically identified as subject to a business confidentiality claim may be disclosed to the requestor without further notice to you.

For each item or class of information that you identify as being subject to your claim, please answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as business confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for business confidentiality, please specify that event.

2. Information submitted to EPA becomes stale over time. Why should the information you claim as business confidential be protected for the time period specified in your answer to question no. 1?

3. What measures have you taken to protect the information claimed as business confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered business confidential?

4. Is the information contained in any publicly available material such as the Internet, publicly available data bases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

5. Has any governmental body made a determination as to the business confidentiality of the information? If so, please attach a copy of the determination.

6. For each category of information claimed as business confidential, explain with specificity why and how release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, please explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

8. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your business confidentiality claim. Conclusory allegations will be given little or no weight in the determination. If you wish to claim any of the information in your response as business confidential, you must mark the response "BUSINESS CONFIDENTIAL" or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of, the procedures set forth in, 40 CFR part 2, subpart B. If you fail to claim the information as business confidential, it may be made available to the requestor without further notice to you.

III. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through *http://www.regulations.gov* or email. Please submit this information by mail to the address identified in the ADDRESSES section of today's notice for inclusion in the non-public CBI docket. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR part 2, subpart B. In addition to the submission of one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

- Identify the notice by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Make sure to submit your comments by the comment period deadline identified.

Dated: February 3, 2014.

Susan E.Bromm,

Director, Office of Federal Activities.

[FR Doc. 2014–02832 Filed 2–7–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before March 12, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov*; and to Cathy Williams, FCC, via email *PRA@fcc.gov mailto:PRA@fcc.gov≤* and to *Cathy.Williams@fcc.gov*. Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the Web page http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0262.

Title: Section 90.179, Shared Use of Radio Stations.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, non-for-profit institutions, and state, local and

tribal government.

Number of Respondents and Responses: 42,000 respondents, 42,000 responses.

Estimated Time per Response: .25 up to .75 hours.

Frequency of Response: Recordkeeping requirement and On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7).

Total Annual Burden: 42,000 hours.

Annual Cost Burden: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission was directed by the United States Congress, in the Balanced Budget Act of 1997, to dedicate 2.4 MHz of electromagnetic spectrum in the 746–806 MHz band for public safety services. Section 90.179 requires that Part 90 licensees that share use of their private land mobile radio facility on non-profit, cost-sharing basis to prepare and keep a written sharing agreement as part of the station records. Regardless of the method of sharing, an up-to-date list of persons who are sharing the station and the basis of their eligibility under Part 90 must be maintained. The requirement is necessary to identify users of the system should interference problems develop. This information is used by the Commission to investigate interference complaints and resolve interference and operational complaints that may arise among the users.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–02829 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 11, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0548.

Title: Section 76.1708, Principal Headend; Sections 76.1709 and 76.1620, Availability of Signals; Section 76.56, Signal Carriage Obligations; Section 76.1614, Identification of Must-Carry Signals.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 5,100 respondents; 61,200 responses.

Estimated Time per Response: 0.5—1 hour.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in in Sections 4(i), 614 and 615 of the Communications Act of 1934, as amended.

Total Annual Burden: 30,600 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: 47 CFR 76.56 requires cable television systems to carry signals of all qualified local Noncommercial Educational (NCE) sting carriage. As a result of this requirement, the following information collection requirements are needed for this collection:

47 CFR 76.1708 requires that the operator of every cable television system shall maintain for public inspection the designation and location of its principal headend. If an operator changes the designation of its principal headend, that new designation must be included in its public file.

47 CFR 76.1709(a) states effective June 17, 1993, the operator of every cable television system shall maintain for public inspection a file containing a list of all broadcast television stations carried by its system in fulfillment of the must-carry requirements pursuant to 47 CFR Section 76.56. Such list shall include the call sign; community of license, broadcast channel number, cable channel number, and in the case of a noncommercial educational broadcast station, whether that station was carried by the cable system on March 29, 1990.

47 CFR 76.1614 and 1709(c) states that a cable operator shall respond in writing within 30 days to any written request by any person for the identification of the signals carried on its system in fulfillment of the requirements of 47 CFR Section 76.56.

47 CFR 76.1620 states that if a cable operator authorizes subscribers to install additional receiver connections, but does not provide the subscriber with such connections, or with the equipment and materials for such connections, the operator shall notify such subscribers of all broadcast stations carried on the cable system which cannot be viewed via cable without a converter box and shall offer to sell or lease such a converter box to such subscribers. Such notification must be provided by June 2, 1993, and annually thereafter and to each new subscriber upon initial installation. The notice, which may be included in routine billing statements, shall identify the signals that are unavailable without an additional connection, the manner for obtaining such additional

connection and instructions for installation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–02827 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 11, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0767.

Title: Sections 1.2110, 1.2111 and 1.2112, Auction and Licensing Disclosures—Ownership and Small Business Status.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, Not-for-profit institutions, and State, local or tribal government.

Number of Respondents: 300 respondents; 300 responses.

Estimated Time per Response: .50 hours—2 hours.

Frequency of Response: On occasion reporting requirement, Third party disclosure requirement, and Recordkeeping requirement.

Total Annual Burden: 450 hours.

Total Annual Costs: $30,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality. However, if applicants want to seek confidential treatment of their information, they may do so under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: A request for extension of this information collection (no change in requirements) will be submitted to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three year clearance from OMB. Beginning first on May 5, 1997, OMB approved under OMB Control No. 3060–0767, the Commission's collections of information pursuant to sections 1.2110, 1.2111, and 1.2112, 47 CFR 1.2110, 1.2111, and 1.2112, and their predecessors, regarding ownership and small business status of parties involved with Commission licenses. The Commission collects this information in several contexts, including when determining the eligibility of applicants to participate in Commission auctions, the eligibility of parties to hold a Commission authorization, the eligibility of parties to whom authorizations are being transferred, and the repayment by authorization holders of small business bidding credits received in Commission auctions. The information requirement will enable the Commission to ensure that no bidder gains an unfair advantage over other bidders in its spectrum auctions and thus enhance the competitiveness and fairness of its auctions. The information collected will be reviewed and, if warranted, referred to the Commission's Enforcement Bureau for possible investigation and administrative action. The Commission may also refer allegations of anticompetitive auction conduct to the Department of Justice for investigation. OMB has approved separately the routine collections of information pursuant to these Commission rules in applications to participate in Commission auctions, FCC Form 175, OMB Control No. 3060–0600, and in Commission licensing applications, FCC Form 601, OMB Control No. 3060–0798. On occasion, the Commission may collect information pursuant to these rules to clarify information provided in these forms or in circumstances to which the standard forms may not directly apply. Accordingly, the Commission requests an extension of the approval of OMB Control No. 3060–0767.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–02828 Filed 2–7–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request Re: Foreign Branching and Investment by Insured State Nonmember Banks

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. As part of its continuing effort to reduce paperwork and respondent burden, the FDIC invites the general public and other Federal agencies to take this opportunity to comment on renewal of an existing information collection, as required by the PRA. On December 6, 2013 (78 FR 73538), the FDIC requested comment for 60 days on renewal of its information collection entitled *Foreign Branching and Investment by Insured State Nonmember Banks,* which is

currently approved under OMB Control No. 3064–0125. No comments were received on the proposal to renew. The FDIC hereby gives notice of submission to OMB of its request to renew the collection.

DATES: Comments must be submitted on or before March 12, 2014.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov* Include the name of the collection in the subject line of the message.
- *Mail:* Leneta G. Gregorie (202–898–3719), Counsel, Room NYA–5050, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Leneta Gregorie, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collections of information:

Title: Foreign Branching and Investment by Insured State Nonmember Banks.

OMB Number: 3064–0125.

Frequency of Response: On occasion.

Affected Public: Insured state nonmember banks.

Estimated Number of Respondents: Recordkeeping—40; reporting—11.

Estimated Time per Response: Recordkeeping—400 hours; reporting—27 hours.

Total Estimated Annual Burden: 16,298 hours.

General Description of Collection: The Federal Deposit Insurance (FDI) Act requires state nonmember banks to obtain FDIC consent to establish or operate a branch in a foreign country, or to acquire and hold, directly or indirectly, stock or other evidence of ownership in any foreign bank or other entity. The FDI Act also authorizes the FDIC to impose conditions for such consent and to issue regulations related thereto. This collection is a direct consequence of those statutory requirements.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 4th day of February 2014.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2014–02712 Filed 2–7–14; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

[Notice 2014–04]

Filing Dates for the Oklahoma Senate Special Elections

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special elections.

SUMMARY: Oklahoma has scheduled special elections to fill the U.S. Senate seat being vacated by Senator Tom Coburn. There are three possible special elections, but only two may be necessary.

- *Primary Election:* June 24, 2014.
- *Possible Runoff Election:* August 26, 2014. In the event that one candidate does not achieve more than 50% of the vote in his/her party's Special Primary Election, the top two vote-getters participate in a Special Runoff Election.
- *General Election:* November 4, 2014.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, 999 E Street NW., Washington, DC 20463; Telephone: (202) 694–1100; Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

Special Primary Only

All principal campaign committees of candidates *only* participating in the Oklahoma Special Primary shall file a Pre-Primary Report on June 12, 2014. (See chart below for the closing date for the report).

Special Primary and General Without Runoff

If only two elections are held, all principal campaign committees of candidates participating in the Oklahoma Special Primary and Special General Elections shall file a Pre-Primary Report on June 12, 2014; a Pre-General Report on October 23, 2014; and a Post-General Report on December 4, 2014. (See chart below for the closing date for each report).

Special Primary and Runoff Elections

If three elections are held, all principal campaign committees of candidates *only* participating in the Oklahoma Special Primary and Special Runoff Elections shall file a Pre-Primary Report on June 12, 2014; and a Pre-Runoff Report on August 14, 2014. (See chart below for the closing date for each report.)

Special Primary, Runoff and General Elections

All principal campaign committees of candidates participating in the Oklahoma Special Primary, Special Runoff and Special General Elections shall file a Pre-Primary Report on June 12, 2014; a Pre-Runoff Report on August 14, 2014; a Pre-General Report on October 23, 2014; and a Post-General Report on December 4, 2014. (See chart below for the closing date for each report.)

Unauthorized Committees (PACs and Party Committees)

Political committees filing on a quarterly basis in 2014 are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Oklahoma Special Primary, Special Runoff or Special General Elections by the close of books for the applicable report(s). (See chart below for the closing date for each report).

Committees filing monthly that make contributions or expenditures in connection with the Oklahoma Special Primary, Special Runoff or Special General Elections will continue to file according to the monthly reporting schedule.

Additional disclosure information in connection with the Oklahoma Special Elections may be found on the FEC Web site at *http://www.fec.gov/info/report_dates.shtml.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and Leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of $17,300 during the special election reporting periods (see charts below for closing date of each period). 11 CFR 104.22(a)(5)(v) and (b).

CALENDAR OF REPORTING DATES FOR OKLAHOMA SPECIAL ELECTIONS

Report	Close of books [1]	Reg. Cert. & overnight mailing deadline	Filing deadline
COMMITTEES INVOLVED IN *ONLY* THE SPECIAL PRIMARY (06/24/14) MUST FILE:			
Pre-Primary	06/04/14	06/09/14	06/12/14
July Quarterly	06/30/14	07/15/14	07/15/14
IF ONLY TWO ELECTIONS ARE HELD, COMMITTEES INVOLVED IN THE SPECIAL PRIMARY (06/24/14) AND SPECIAL GENERAL (11/04/14) MUST FILE:			
Pre-Primary	06/04/14	06/09/14	06/12/14
July Quarterly	06/30/14	07/15/14	07/15/14
October Quarterly	09/30/14	10/15/14	10/15/14
Pre-General	10/15/14	10/20/14	10/23/14
Post-General	11/24/14	12/04/14	12/04/14
Year-End	12/31/14	01/31/15	01/31/15 [2]
IF ONLY TWO ELECTIONS ARE HELD, COMMITTEES INVOLVED IN *ONLY* THE SPECIAL GENERAL (11/04/14) MUST FILE:			
Pre-General	10/15/14	10/20/14	10/23/14
Post-General	11/24/14	12/04/14	12/04/14
Year-End	12/31/14	01/31/15	01/31/15 [2]
IF THREE ELECTIONS ARE HELD, COMMITTEES INVOLVED IN THE SPECIAL PRIMARY (06/24/14) AND SPECIAL RUNOFF (08/26/14) MUST FILE:			
Pre-Primary	06/04/14	06/09/14	06/12/14
July Quarterly	06/30/14	07/15/14	07/15/14
Pre-Runoff	08/06/14	08/11/14	08/14/14
October Quarterly	09/30/14	10/15/14	10/15/14
IF THREE ELECTIONS ARE HELD, COMMITTEES INVOLVED IN *ONLY* THE SPECIAL RUNOFF (08/26/14) MUST FILE:			
Pre-Runoff	08/06/14	08/11/14	08/14/14
October Quarterly	09/30/14	10/15/14	10/15/14
COMMITTEES INVOLVED IN THE SPECIAL PRIMARY (06/24/14), SPECIAL RUNOFF (08/26/14) AND SPECIAL GENERAL (11/04/14) MUST FILE:			
Pre-Primary	06/04/14	06/09/14	06/12/14
July Quarterly	06/30/14	07/15/14	07/15/14
Pre-Runoff	08/06/14	08/11/14	08/14/14
October Quarterly	09/30/14	10/15/14	10/15/14
Pre-General	10/15/14	10/20/14	10/23/14
Post-General	11/24/14	12/04/14	12/04/14
Year-End	12/31/14	01/31/15	01/31/15 [2]
IF THREE ELECTIONS ARE HELD, COMMITTEES INVOLVED IN *ONLY* THE SPECIAL GENERAL (11/04/14) MUST FILE:			
Pre-General	10/15/14	10/20/14	10/23/14
Post-General	11/24/14	12/04/14	12/04/14

[1] These dates indicate the end of the reporting period. A reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee with the Commission up through the close of books for the first report due.

[2] Notice that this filing deadline falls on a weekend or federal holiday. Filing deadlines are not extended when they fall on nonworking days. Accordingly, reports filed by methods other than Registered, Certified or Overnight Mail, or electronically, must be received before the Secretary of the Senate Public Records Office's (or for committees not supporting only Senate candidates, the Commission's) close of business on the last business day before the deadline.

Dated: February 4, 2014.
On behalf of the Commission,
Lee E. Goodman,
Chairman, Federal Election Commission.
[FR Doc. 2014–02720 Filed 2–7–14; 8:45 am]
BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations and Terminations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked or terminated for the reason shown pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 3469NF.
Name: IEC (America) Inc.
Address: 2373 208th Street, Unit F–4, Torrance, CA 90501.
Date Revoked: October 31, 2013.
Reason: Failed to maintain valid bonds.

License No.: 004306F.
Name: International Transport Services, Inc.
Address: 19987 Commerce Parkway, Cleveland, OH 44130.
Date Revoked: October 12, 2013.
Reason: Failed to maintain a valid bond.

License No.: 8504N.
Name: Hyun Dae Trucking Co., Inc.
Address: 3022 S. Western Avenue, Los Angeles, CA 90018.
Date Revoked: November 30, 2013.
Reason: Failed to maintain a valid bond.

License No.: 11042N.
Name: TSJ Consolidators, Inc.
Address: 13737 Artesia Blvd., #107, Cerritos, CA 90703.
Date Revoked: November 8, 2013.
Reason: Voluntary Surrender of License.

License No.: 011263N.
Name: Bugatti Freight Int'l (USA) Inc.
Address: 150–40 183rd Street, Suite 208, Jamaica, NY 11413.
Date Revoked: November 16, 2013.
Reason: Failed to maintain a valid bond.

License No.: 015574N
Name: WW Messenger & Shipping Co.
Address: 150 Main Street, Unit 9, Orange, NJ 07050
Date Revoked: October 16, 2013.
Reason: Failed to maintain a valid bond.

License No.: 15663N.
Name: T.J.D. International, Inc.
Address: 150 River Road, Suite 4H, Montville, NJ 07045.
Date Revoked: October 3, 2013.
Reason: Failed to maintain a valid bond.

License No.: 16464N.
Name: NE.W.S. Transportation Co., Inc. dba NE.W.S. Express.
Address: 1161 Sandhill Avenue, Suite A, Carson, CA 90746
Date Revoked: October 14, 2013.
Reason: Failed to maintain a valid bond.

License No.: 16854N.
Name: YT Youngtrans, Inc. dba Youngtrans.
Address: 167–55 148th Avenue, Jamaica, NY 11434.
Date Revoked: November 18, 2013.
Reason: Voluntary Surrender of License.

License No.: 017603N.
Name: WP Logistics Inc.
Address: 18747 S. Laurel Park Road, Rancho Dominguez, CA 90220.
Date Revoked: November 4, 2013.
Reason: Voluntary Surrender of License.

License No.: 018270N.
Name: Montero Shipping Corp.
Address: 2341 Hoffman Street, Bronx, NY 10458.
Date Revoked: November 8, 2013.
Reason: Failed to maintain a valid bond.

License No.: 18567N.
Name: CL America, LLC.
Address: 18881 Von Karman Avenue, Suite 1450, Irvine, CA 92612.
Date Revoked: September 30, 2013.
Reason: Failed to maintain a valid bond.

License No.: 018732N.
Name: Transways Logistics International Inc.
Address: 149–23 183rd Street, Suite 101, Jamaica, NY 11413.
Date Revoked: September 30, 2013.
Reason: Failed to maintain a valid bond.

License No.: 018928N.
Name: Evergreen International Group, LLC.
Address: 1937 Pontius Avenue, Suite 301, Los Angeles, CA 90025.
Date Revoked: October 3, 2013.
Reason: Failed to maintain a valid bond.

License No.: 018958N.
Name: Transec International, Inc.
Address: 10306 NE 10th Street, Bellevue, WA 98004.
Date Revoked: October 23, 2013.
Reason: Failed to maintain a valid bond.

License No.: 019073F.
Name: Elizabeth A. Ohanneson dba Ohanneson Freight Forwarding
Address: 165 North Redwood Drive, Suite 201, San Rafael, CA 94903.
Date Revoked: October 29, 2013.
Reason: Failed to maintain a valid bond.

License No.: 019089N.
Name: Sys-Tems Logistix, Inc.
Address: 3850 Three Mile Lane NE., McMinnville, OR 97128.
Date Revoked: June 7, 2008.
Reason: Failed to maintain a valid bond.

License No.: 019563NF.
Name: Tarraf Inc. dba Tarraf Shipping.
Address: 15800 Tireman Street, Detroit, MI 48228.
Date Revoked: November 18, 2013.
Reason: Voluntary Surrender of License.

License No.: 019628NF.
Name: SBS Worldwide, Inc. dba SBS Worldwide (NYC) dba SBS Worldwide (CHS) dba SBS Worldwide Atlanta dba SBS Worldwide (Chicago).
Address: 100 Walnut Street, Suite 405, Clark, NJ 07066.
Date Revoked: November 18, 2013.
Reason: Voluntary Surrender of License.

License No.: 019703N.
Name: Taurus Line, Inc. dba Taurus Marine Line
Address: 17110 Royal Palm Blvd., Suite 3, Weston, FL 33326.
Date Revoked: November 7, 2013.
Reason: Voluntary Surrender of License.

License No.: 019901N.
Name: Ambiorix Cargo Express Inc.
Address: 453 East 167th Street, Bronx, NY 10456.
Date Revoked: October 16, 2013.
Reason: Failed to maintain a valid bond.

License No.: 020274N.
Name: United Presidents Line, Inc.
Address: 2698 Junipero Avenue, Suite 118, Signal Hills, CA 90755.
Date Revoked: October 31, 2013.
Reason: Failed to maintain a valid bond.

License No.: 020953F.
Name: Gold Cargo Freight, Corp.
Address: 8233 NW 68th Street, Miami, FL 33166.
Date Revoked: October 13, 2013.
Reason: Failed to maintain a valid bond.

License No.: 020992N.
Name: Korea International Logistics Co., Ltd.
Address: 1418 Beaver Ruin Road, Norcross, GA 30093.
Date Revoked: November 8, 2013.
Reason: Failed to maintain a valid bond.

License No.: 022188NF.
Name: Optima Cargo & Logistics Inc. dba Optima Express.

Address: 9428 NW 13th Street, Bay #53, Doral, FL 33172.
Date Revoked: OFF—December 8, 2013 & NVOCC—November 22, 2013.
Reason: Failed to maintain valid bonds.

License No.: 022418NF
Name: Manray Express Freight Systems, Inc.
Address: 7000 NW 32nd Avenue, Miami, FL 33147.
Date Revoked: November 14, 2013.
Reason: Failed to maintain valid bonds.

License No.: 022506NF.
Name: Daudry Business Group, Corp dba Don Envion dba Adam Logistics.
Address: 5463 NW 72nd Avenue, Miami, FL 33166.
Date Revoked: October 24, 2013.
Reason: Failed to maintain valid bonds.

License No.: 022604N.
Name: Tri-Vi-U.S. Logistics Ltd.
Address: 170 E. Sunrise Highway, Valley Stream, NY 11580.
Date Revoked: October 3, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023467F.
Name: Freightmate NY Inc.
Address: 146 Spencer Street, Suite 4005, Brooklyn, NY 11205.
Date Revoked: November 20, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023518F.
Name: Bulk Cargo Services & Logistics Inc.
Address: 15400 NE. 103rd Drive, Vancouver, WA 98682.
Date Revoked: November 27, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023604F.
Name: Caterpillar Logistics Services LLC.
Address: 7915 North Hale Avenue, Peoria, IL 61615.
Date Revoked: November 22, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023613F.
Name: NGL International, LLC.
Address: 2121 Abbott Road, Suite 202, Anchorage, AK 99507.
Date Revoked: October 18, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023959F.
Name: Master Transportation Cargo, LLC.
Address: 9600 NW 38th Street, Suite 310, Doral, FL 33178.
Date Revoked: October 18, 2013.
Reason: Failed to maintain a valid bond.

License No.: 024070F.
Name: Mohammad A. Bagegni dba Coastal Auto Exporters.
Address: 23 Balcom Road, Pelham, NH 03076.
Date Revoked: November 16, 2013.
Reason: Failed to maintain a valid bond.

License No.: 024098N.
Name: Albarq Shipping Services Inc.
Address: 8151 Electric Avenue, Stanton, CA 90680.
Date Revoked: October 23, 2013.
Reason: Failed to maintain a valid bond.

License No.: 024117N.
Name: A & E Logistics, Inc.
Address: 3011 S. Poplar Avenue, Chicago, IL 60608.
Date Revoked: November 28, 2013.
Reason: Failed to maintain a valid bond.

License No.: 024166NF.
Name: US Com Express, LLC.
Address: 1420 Francisco Street, Torrance, CA 90501.
Date Revoked: October 4, 2013.
Reason: Failed to maintain valid bonds.

License No.: 024540NF.
Name: GB America, LLC.
Address: 19100 Von Karman Avenue, Suite 370, Irvine, CA 92612.
Date Revoked: September 30, 2013.
Reason: Failed to maintain valid bonds.

Sandra L. Kusumoto,
Director, Bureau of Certification and Licensing.
[FR Doc. 2014–02788 Filed 2–7–14; 8:45 am]
BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 7, 2014.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Apollo Bancshares, Inc.,* Miami, Florida; to acquire 100 percent of the voting shares of First Bank of Miami Shares, Inc., and thereby indirectly acquire voting shares of First Bank of Miami, both in Coral Gables, Florida.

Board of Governors of the Federal Reserve System, February 5, 2014.
Michael J. Lewandowski,
Associate Secretary of the Board.
[FR Doc. 2014–02783 Filed 2–7–14; 8:45 am]
BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology

Announcement of Requirements and Registration for "Digital Privacy Notice Challenge"

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.
Award Approving Official: Karen DeSalvo, National Coordinator for Health Information Technology.
ACTION: Notice.

SUMMARY: The HIPAA Privacy Rule gives individuals a fundamental right to be informed of the privacy practices of health plans and health care providers, as well as to be informed of their privacy rights with respect to their personal health information. Health plans and covered health care providers are required to develop and distribute a notice that provides a clear, user friendly explanation of these rights and practices.[1] In practice, however, many patients have found that these notices

[1] 45 CFR 164.520.

can be difficult to read and poorly comprehended.[2]

The Office of the National Coordinator for Health Information Technology (ONC) recently collaborated with the Office for Civil Rights (OCR) to develop model notices of privacy practices (NPP) that clearly convey the required information to patients in an accessible format. These *model notices* can be customized by covered entities (doctors, hospitals and other health care providers covered by HIPAA who maintain patient data, health plans) and then printed for office display and distributed to patients.

The new model notice resources offer an opportunity to improve what covered entities display online. Research shows that online privacy policies are often not read or well-understood by the general public.[3] As in the case of privacy notices displayed in medical offices, if patients cannot understand what they are reading online, they will not be properly informed of their privacy rights, including their right to access their health information. A patient's understanding of his or her privacy rights is an important component of quality health care and can impact patient-provider communication as well as patient engagement in health care.

The Digital Privacy Notice Challenge leverages the consumer tested and preferred content and formats developed recently as part of the joint ONC/OCR model NPP project and provides an award to the creators of the best online versions of an NPP. Out-of-the-box thinking could be effectively applied to the challenge of creating an online NPP that patients would actually read and understand, helping to break down the barriers to patients taking greater control of their own health and health care. We hope to bring a variety of creative minds to the task of developing a patient friendly resource, as well as enable users to interact with the proposed notices and identify the most effective approaches.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Public L. 111–358).

DATES:

- Submission period begins: February 7, 2014
- Submission period ends: April 7, 2014
- Winners announced: Event TBD May-June, 2014

FOR FURTHER INFORMATION CONTACT: Adam Wong, 202–720–2866

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition

The Challenge is a call for designers, developers, and patient privacy experts to create an online model notice of privacy practices that is compelling, readable, and understandable by patients and is easily integrated into existing entity Web sites. Submissions will use the content and design elements developed recently as part of the joint ONC/OCR *paper-based model NPP project.* Submitters are challenged to take the model language and format(s) and develop effective approaches to integrating them into an online interface. The module, or generator, is intended to live on GitHub and be made available open-source such that any organization can implement it on its Web site.

The Submission must:

- Be coded in JavaScript for the interaction piece (as a JQuery plugin, Node.JS module, or standalone script) and HTML/CSS for the presentation layer.
- Use the content developed jointly by ONC and OCR, available at *http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html.* The formatting design elements of the paper notices were consumer-tested and should be looked to as a guide, but successful submissions will factor in the differences between reading and consuming content on paper versus online.
- Allow organizations using it to customize the content, consistent with the options made available through the paper-based model.

The intent of the challenge is to design a model digital notice that creatively informs and educates the user, so simply cutting-and-pasting the content into an online document will not be sufficient to win an award.

At the end of the submission period, Submissions will be posted on the challenge Web site for a public voting period of two weeks.

In addition to the functioning generator, Solvers must submit a slide deck of no more than seven slides that describes how the submission functions, how to install and operate the generator, the system requirements to run the generator, and addresses the application requirements.

Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by the Office of the National Coordinator for Health Information Technology.

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) May not be a Federal entity or Federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) Shall not be an employee of Office of the National Coordinator for Health IT.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Entrants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

Registration Process for Participants

To register for this Challenge, participants can access *http://www.challenge.gov* and search for "Digital Privacy Notice Challenge."

[2] https://www.privacyrights.org/ar/HIPAA-Reading.htm.

[3] Turow, Hoofnagle, Mulligan, Good and Grossklags. The Federal Trade Commission and Consumer Privacy in the Coming Decade. *I/S—A Journal of Law and Policy for the Information Society.* 740. (2008).

Prize

- Total: $25,000 in prizes
- First Place: $15,000
- Second Place: $7,000
- Third Place: $3,000

Payment of the Prize

Prize will be paid by contractor.

Basis upon Which Winner Will be Selected

The review panel will make selections based upon the following criteria:

- Accurate use of model NPP content
- Use of best practices in presenting web content for consumption, including use of plain/understandable writing in any additional framing language
- Visual appeal
- Capacity to link to other relevant covered entity content
- Results from public voting period

In order for an entry to be eligible to win this Challenge, it must meet the following requirements:

1. General—Contestants must provide continuous access to the tool, a detailed description of the tool, instructions on how to install and operate the tool, and system requirements required to run the tool (collectively, "Submission")

2. Acceptable platforms—The tool must be designed for use with existing web, mobile web, electronic health record, or other platform for supporting interactions of the content provided with other capabilities.

3. Section 508 Compliance—Contestants must acknowledge that they understand that, as a pre-requisite to any subsequent acquisition by FAR contract or other method, they are required to make their proposed solution compliant with Section 508 accessibility and usability requirements at their own expense. Any electronic information technology that is ultimately obtained by HHS for its use, development, or maintenance must meet Section 508 accessibility and usability standards. Past experience has demonstrated that it can be costly for solution-providers to "retrofit" solutions if remediation is later needed. The HHS Section 508 Evaluation Product Assessment Template, available at *http://www.hhs.gov/od/vendors/index.html,* provides a useful roadmap for developers to review. It is a simple, web-based checklist utilized by HHS officials to allow vendors to document how their products do or do not meet the various Section 508 requirements.

4. No HHS or ONC logo—The app must not use HHS', ONC's, or OCR's logos or official seals in the Submission, and must not claim endorsement.

5. Functionality/Accuracy—A Submission may be disqualified if it fails to function as expressed in the description provided by the user, or if it provides inaccurate or incomplete information.

6. Security—Submissions must be free of malware. Contestant agrees that ONC may conduct testing on the app to determine whether malware or other security threats may be present. ONC may disqualify the Submission if, in ONC's judgment, the app may damage government or others' equipment or operating environment.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Winning entries as determined by ONC will be licensed to all under the *Apache License 2.0.*

Authority: 15 U.S.C. 3719.

Dated: February 3, 2014.

Karen DeSalvo,

National Coordinator for Health Information Technology.

[FR Doc. 2014–02785 Filed 2–7–14; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Surgeon General of the United States Public Health Service, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that a meeting is scheduled to be held for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the "Advisory Group"). The meeting will be open to the public. Information about the Advisory Group and the agenda for this meeting can be obtained by accessing the following Web site: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html*

DATES: The meeting will be held on February 26, 2014 from 3:00–5:00 p.m. EST via teleconference. More information about the meeting can be found at: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html*

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave. SW.; Washington, DC 20201; 202–205–9517; *prevention.council@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary federal advisory committee that was initially established under Executive Order 13544, dated June 10, 2010, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. The Advisory Group was terminated on September 30, 2012, by Executive Order 13591, dated November 23, 2011. Authority for the Advisory Group to be re-established was given under Executive Order 13631, dated December 7, 2012. Authority for the Advisory Group to continue to operate until September 30, 2015 was given under Executive Order 13652, dated September 30, 2013.

The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council.

It is authorized for the Advisory Group to consist of not more than 25 non-federal members. The Advisory Group currently has 22 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine. During this meeting, the Advisory Group will review recommendations they have developed to be submitted to the next Surgeon General.

Members of the public who wish to attend must register by 12:00 p.m. EST on February 21, 2014. Individuals should register for public attendance at *prevention.council@hhs.gov* by providing your full name and affiliation. The public will have the opportunity to provide comments to the Advisory Group; public comment will be limited to 3 minutes per speaker. Registration via email (*prevention.council@hhs.gov*) is also required for the public comment session. Any member of the public who wishes to have printed materials distributed to the Advisory Group for this scheduled meeting should submit

material to *prevention.council@hhs.gov* no later than 12:00 p.m. EST on February 21, 2014.

Dated: January 23, 2014.

Corinne M. Graffunder,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, Office of the Surgeon General.

[FR Doc. 2014–02784 Filed 2–7–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10433]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: the necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 12, 2014.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs; Attention: CMS Desk Officer; Fax Number: (202) 395–5806 *or*; Email: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualifies Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* The purpose of this collection is to ensure that Qualified Health Plans must meet certain minimum certification standards, such as those pertaining to essential community providers, essential health benefits, and actuarial value. In order to meet those standards, the Exchange is responsible for collecting data and validating that QHPs meet these minimum requirements as described in the Exchange rule under 45 CFR parts 155 and 156, based on the Affordable Care Act, as well as other requirements determined by the Exchange. In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS–9975–F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), published in March 23, 2012, have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 provide further reporting requirements. Based on experience with the first year of data collection, we propose revisions to data elements being collected and the burden estimates for years two and three. *Form Number:* CMS–10433 (OCN: 0938–1187); *Frequency:* Once; *Affected Public:* Individuals or Households; *Number of Respondents:* 27,225; *Total Annual Responses:* 27,225; *Total Annual Hours:* 217,225 hours. (For questions regarding this collection contact Danielle Chestang at 410–786–7815).

Dated: February 5, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–02787 Filed 2–7–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE–75 Tribal Child Support Enforcement Program Annual Data Report.

OMB No.: 0970–0320.

Description: The data collected by form OCSE–75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV–D of the Social Security Act are required to report program status and accomplishments in an annual narrative report and submit the OCSE–75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–75	60	1	60	3,600

Estimated Total Annual Burden Hours: 3,600.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–02684 Filed 2–7–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Community Living

Proposed Information Collection Activity; Comment Request; State Developmental Disabilities Council 5-Year State Plan

AGENCY: Administration for Community Living, Administration on Intellectual and Developmental Disabilities, HHS.

ACTION: Notice.

SUMMARY: A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) by any amendments. The State Plan will be used (2) by the Council as a planning document; (3) by the citizenry of the State as a mechanism for commenting on the plans of the Council; (4) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (e.g., during site visits), and as a support for management decision making.

DATES: Submit written comments on the collection of information by April 11, 2014.

ADDRESSES: Submit written comments on the collection of information by email to: *Valerie.Bond@aoa.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Valerie Bond, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4302, Washington, DC 20201, 202–690–5841.

SUPPLEMENTARY INFORMATION: In compliance with the requirements of Section 506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to: Valerie Bond, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program, One Massachusetts Avenue NW., Room 4302, Washington, DC 20201.

The Department specifically requests comments on: (a) Whether the proposed Collection of information is necessary for the proper performance of the function of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden information to be collected; and (e) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection technique comments and or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Respondents: 56 State Developmental Disabilities Councils.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan	56	1	367	20,552

Estimated Total Annual Burden Hours: 20,552.

Dated: February 4, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–02839 Filed 2–7–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1394]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0470. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910–0470)—Extension

The "Guidance for Industry on Special Protocol Assessment" describes Agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the Agency to act on such requests. The guidance provides information on how the Agency interprets and applies provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol, and (2) the submission of a request for special protocol assessment.

Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in Agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the Agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

Request for Special Protocol Assessment

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the Agency in triplicate with Form FDA 1571 attached. The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via fax to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the Agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via fax to the appropriate division in CDER or CBER to enable Agency staff to prepare for the arrival of the protocol for assessment. The Agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the appropriate Agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the Agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

Notification for a Carcinogenicity Protocol. Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER

estimates that it will receive approximately 50 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 23 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 300 requests for special protocol assessment per year from approximately 145 sponsors. CBER estimates that it will receive approximately 14 requests from approximately 11 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the Agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

In the **Federal Register** of November 18, 2013 (78 FR 69093), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification for carcinogenicity protocols	24	2.1	51	8	408
Requests for special protocol assessment	156	2	314	15	4,710
Total					5,118

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02754 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the FDA Safety Communication Readership Survey.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Safety Communication (Formerly Known as Public Health Notification) Readership Survey—(OMB Control Number 0910–0341)—Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) gives FDA authority to disseminate information concerning suspected or imminent danger to public health by any regulated product. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) also

authorizes FDA to conduct research relating to health information.

FDA's Center for Devices and Radiological Health (CDRH) carries out FDA's regulatory responsibilities regarding medical devices and radiological products. CDRH must be able to effectively communicate risk to health care practitioners, patients, caregivers, and consumers when there is a real or suspected threat to the public's health. CDRH uses safety communications to transmit information concerning these risks to user communities. Safety communications are released and available to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers, as well as patients, caregivers, consumers, and patient advocacy groups. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release safety communications.

FDA seeks to evaluate the clarity, timeliness, and impact of safety communications by surveying a sample of recipients to determine the impact of safety communications on the knowledge of the recipients. Understanding how the target audiences view these publications will aid in determining what, if any, changes should be considered in their content, format, and method of dissemination. The collection of this data is an important step in determining how well CDRH is communicating risk. The results from this survey will emphasize the quality of the safety communications and customer satisfaction. This will enable us to better serve the public by improving the effectiveness of safety communications.

We updated the title of the survey from "FDA Public Health Notification Readership Survey" to "FDA Safety Communication Readership Survey" to accurately reflect the information that is being collected.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Public Health Notification Readership Survey	300	3	900	0.17 (10 minutes)	153

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the FDA Safety Communication program, it is estimated that an average of three collections will be conducted per year. The average burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey.

Dated: February 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02752 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60 (OMB Control Number 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by the FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates

used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with "due diligence."

The statute defines due diligence as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." As provided in § 60.30(c), a due diligence petition "shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence." Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 15 requests for revision of the regulatory review period have been submitted under § 60.24(a). For 2010, 2011, and 2012, a total of three requests have been submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

In the **Federal Register** of November 14, 2013 (78 FR 68454), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24(a)	1	1	1	100	100
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total					160

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02753 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0039 (Formerly 2006D–0408)]

Annual Reports for Approved Premarket Approval Applications, Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Annual Reports for Approved Premarket Approval Applications (PMA)." The purpose of this guidance is to describe the information required to be included in an annual report for an approved PMA, additional information requirements that may be imposed by an approval order, and FDA's recommendations for the level of detail the applicant should provide in the annual report. It also identifies the steps FDA staff generally takes when reviewing annual reports, the resources available to assist staff in their reviews, and the regulatory actions they may recommend after reviewing annual reports.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Annual Reports for Approved Premarket Approval Applications (PMA)" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

I. Background

In the **Federal Register** of October 26, 2006 (71 FR 62595), FDA announced the availability of its draft guidance entitled, "Annual Reports for Approved Premarket Approval Applications (PMA)," and invited interested persons to comment on the document. FDA received several comments, most of which sought additional clarification and recommendations about the level of detail and format of annual reports. We

considered all of the comments received and revised the guidance where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on annual reports for PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Device and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from the Center for Biologics Evaluation and Research (CBER) at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive "Annual Reports for Approved Premarket Approval Applications (PMA)," you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1585 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814.82(a)(7) and 814.84(b) have been approved under OMB control number 0910–0231.

Under section 3506(c)(2)(A) of the PRA, FDA provided a 60-day notice concerning the proposed collection of information set forth in the draft guidance (71 FR 62595, October 26, 2006). In response to the notice, FDA received several comments pertaining to the information collection.

Comments noted that for changes previously submitted in a regulatory submission, requiring a rationale for each change is burdensome and duplicative because FDA already has this information. In response to this comment, FDA modified the guidance to request only limited information for changes that were submitted as either a PMA supplement or 30-day notice, including supplement number and the status of the document.

Comments requested clarification of the type of information, data, and level of detail that need to be provided. In response, FDA removed columns from the proposed "Changes Table" in the guidance, including columns for validation testing, implementation date, approval date, and risk analysis.

As a result of modifications made to the guidance in response to comments, the guidance no longer imposes an information collection burden additional to that previously approved in OMB control number 0910–0231. FDA is therefore no longer requesting approval of an additional information collection.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02765 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (Formerly Docket No. 2007D–0396)

Serious Drug-Induced Liver Injury: Who Gets It? Who Doesn't? Why?; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled "Serious Drug-Induced Liver Injury (DILI): Who Gets It? Who Doesn't? Why?" This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. Its purpose is to discuss, debate, and share views among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 19, 2014, from 8 a.m. to 6 p.m., and March 20, 2014, from 8 a.m. to 4 p.m.

ADDRESSES: The conference will take place at the College Park Marriott Hotel & Conference Center, 3501 University Blvd., Hyattsville, MD 20783. The hotel's phone number is 301–985–7300.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4482, Silver Spring, MD 20993–0002, 301–796–0518, *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" (74 FR 38035; July 30, 2009). This guidance explained that DILI was the most frequent cause of safety-related drug marketing withdrawals for the past 50 years and that hepatotoxicity has limited use of many drugs that have been approved and prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration, and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. It suggests some "stopping rules" for interrupting drug treatment, and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009. FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.

II. Conference Information

The purpose of the 2014 conference is to invite participants to present their data and views, and to hold open discussion.

A. Registration

A registration fee ($600 for industry registrants and $300 for Federal government and academic registrants) will be charged to help defray the costs of renting meeting spaces and the meals and snacks provided. The fee will also be used to cover travel costs incurred by invited academic (but not government or industry) speakers and other expenses. The registration process will be handled by C-Path, an independent, nonprofit organization established in 2005 with public and private philanthropic support from the southern Arizona community, Science Foundation Arizona, and FDA.

Additional information on the conference, program, and registration procedures may be obtained on the Internet at *http://www.c-path.org* and *http://www.fda.gov* and typing "liver toxicity" into the search box. (FDA has verified the C-Path Web site address, but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

B. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Material presented at past programs (from 1999 to 2013) may be accessed at *www.aasld.org*. Click on "Education/Training" and then scroll down to "Drug Induced Liver Injury 2013 Program."

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02755 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Clinical Seq. for UDN.

Date: February 28, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lita Proctor, Ph.D., Extramural Research Programs Staff, Program Director, Human Microbiome Project, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20892, 301–496–4550, *proctorlm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: February 4, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02687 Filed 2–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Center Core Application Review.

Date: March 10, 2014.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 5635 Fishers Lane, Terrace Level, Rockville, MD.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Career Development and Pathways to Independence Grant Applications.

Date: March 10, 2014.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Rockville, Maryland, Terrace Level, 5635 Fisher's Lane, Rockville, MD 20892.

Contact Person: Jeanette M Hosseini, Ph.D., Scientific Review Officer, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS).

Dated: February 4, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02688 Filed 2–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Implication of CR diet for validation aging related ailments and disorders.

Date: March 3, 2014.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; CELL DEAD I.

Date: March 11, 2014.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: February 4, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02686 Filed 2–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Gamma-Dynacare Medical Laboratories, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190.

HHS-Certified Laboratories

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc.,160 Elmgrove Park,Rochester, NY 14624.585–429–2264.

Aegis Analytical Laboratories, Inc.,345 Hill Ave.,Nashville, TN 37210,615–255–2400,(Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories).

Alere Toxicology Services,1111 Newton St.,Gretna, LA 70053,504–361–8989/800–433–3823,(Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alere Toxicology Services,450 Southlake Blvd.,Richmond, VA 23236,804–378–9130,(Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory,11401 I–30,Little Rock, AR 72209–7056,501–202–2783,(Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab,8433 Quivira Road,Lenexa, KS 66215–2802,800–445–6917.

Doctors Laboratory, Inc.,2906 Julia Drive,Valdosta, GA 31602,229–671–2281.

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023.

Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem

Laboratories, Inc., a Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., a member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244, MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7.

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories).

Redwood Toxicology Laboratory, 3650 Westwind Blvd., Santa Rosa, CA 95403, 707–570–4434.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276.

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Cathy J. Friedman,

Public Health Analyst, SAMHSA.

[FR Doc. 2014–02820 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2013–0067]

Sector Outreach and Programs Division Online Meeting Registration Tool

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-day notice and request for comments; Renewal Information Collection Request: 1670–0019.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office Of Infrastructure Protection (IP), Sector Outreach and Programs Division (SOPD), will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until April 11, 2014. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to DHS/NPPD/IP/SOPD, 245 Murray Lane SW., Mail Stop 0608, Arlington, VA 20598–0640. Emailed requests should go to Nohemi Zerbi, *nohemi.zerbi@hq.dhs.gov.* Written comments should reach the contact person listed no later than April 11, 2014. Comments must be identified by "DHS–2011–0012"and may be submitted by *one* of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.*
- Email: Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

SUPPLEMENTARY INFORMATION: On behalf of DHS, NPPD/IP manages the Department's program to protect the Nation's 16 critical infrastructure sectors by implementing the National Infrastructure Protection Plan (NIPP) 2013, Partnering for Critical Infrastructure Security and Resilience. Pursuant to Presidential Policy Directive 21 on *Critical Infrastructure Security and Resilience* (February 2013), each sector is assigned a Sector-Specific

Agency (SSA) to oversee Federal interaction with the array of sector security partners, both public and private. An SSA is responsible for leading a unified public-private sector effort to develop, coordinate, and implement a comprehensive physical, human, and cybersecurity strategy for its assigned sector. SOPD executes the SSA responsibilities for the six critical infrastructure sectors assigned to IP: Chemical; Commercial Facilities; Critical Manufacturing; Dams; Emergency Services; and Nuclear Reactors, Materials, and Waste (Nuclear).

The mission of SOPD is to enhance the resiliency of the Nation by leading the unified public-private sector effort to ensure its assigned critical infrastructure are prepared, more secure, and safer from terrorist attacks, natural disasters, and other incidents. To achieve this mission, SOPD leverages the resources and knowledge of its critical infrastructure sectors to develop and apply security initiatives that result in significant, measurable benefits to the Nation.

Each SOPD branch builds sustainable partnerships with its public and private sector stakeholders to enable more effective sector coordination, information sharing, and program development and implementation. These partnerships are sustained through the Sector Partnership Model, described in the NIPP 2013 pages 10–12.

Information sharing is a key component of the NIPP Partnership Model, and DHSDRS sponsored conferences are one mechanism for information sharing. To facilitate conference planning and organization, SOPD established an event registration tool for use by all of its branches. The information collection is voluntary and is used by the SSAs within the SOPD. The six SSAs within SOPD use this information to register public and private sector stakeholders for meetings hosted by the SSA. SOPD will use the information collected to reserve space at a meeting for the registrant; contact the registrant with a reminder about the event; develop meeting materials for attendees; determine key topics of interest; and efficiently generate attendee and speaker nametags. Additionally, it will allow SOPD to have a better understanding of the organizations participating in the critical infrastructure protection partnership events. By understanding who is participating, the SSA can identify portions of a sector that are underrepresented, and the SSA could then target that underrepresented sector elements through outreach and awareness initiatives.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Sector Outreach and Programs Division.

Title: Sector Outreach and Programs Division Online Meeting Registration Tool.

OMB Number: 1670.

Frequency: Annually.

Affected Public: Federal, state, local, tribal, and territorial government personnel; private sector members.

Number of Respondents: 1000 respondents (estimate).

Estimated Time per Respondent: 3 minutes.

Total Burden Hours: 50 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $7200.00.

Total Burden Cost (operating/maintaining): $8350.44.

Dated: February 4, 2014.

Scott Libby,

Deputy Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2014–02845 Filed 2–7–14; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3366–EM; Docket ID FEMA–2014–0003]

West Virginia; Amendment No. 2 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of West Virginia (FEMA–3366–EM), dated January 10, 2014, and related determinations.

DATES: *Effective Date:* January 20, 2014.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective January 20, 2014.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2014–02727 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Laboratory Service, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Laboratory Service, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Laboratory Service, Inc., has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 7, 2011.

DATES: *Effective Dates:* The accreditation and approval of Laboratory Service, Inc., as a commercial gauger and laboratory became effective on September 7, 2011. The next triennial inspection date will be scheduled for September 2014.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Laboratory Service, Inc., 11731 Port Road, Seabrook, TX 77586, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Laboratory Service, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Laboratory Service, Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–08	ASTM D 86	Standard Test Method for Distillation of Petroleum Products at Atmoshpheric Pressure.
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
	ASTM D 1364	Standard Test Method for Water in Volatile Solvents (Karl Fischer Reagent Titration Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf.

Dated: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02789 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Oiltest, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Oiltest, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Oiltest, Inc., has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of May 17, 2012.

DATES: *Effective Dates:* The accreditation and approval of Oiltest, Inc., as a commercial gauger and laboratory became effective on May 17, 2012. The next triennial inspection date will be scheduled for May 2015.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Oiltest, Inc., 2718 Westside Drive, Pasadena, TX 77502, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Oiltest, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
8	Sampling.
11	Physical property.
17	Maritime measurement.

Oiltest, Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–03	ASTM D 4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	ASTM D 95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.

CBPL No.	ASTM	Title
27–06	ASTM D 473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–11	ASTM D 445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (the Calculation of Dynamic Velocity).
27–13	ASTM D 4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	ASTM D 5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	ASTM D 93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.*http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02794 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory.

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc., has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of September 27, 2013.

DATES: *Effective Dates:* The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on September 27, 2013. The next triennial inspection date will be scheduled for September 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 1800 Dabney Drive, Pasadena, TX 77536, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Camin Cargo Control, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature Determination.
12	Calculations.
17	Maritime Measurements.
4	Proving Systems.
5	Metering.
8	Sampling.
10	Sediment & Water.
11	Physical Property data.

Camin Cargo Control, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–01	ASTM D–287	Standard test method for API Gravity of crude petroleum products and petroleum products (Hydrometer Method).
27–08	ASTM D–86	Standard test method for distillation of petroleum products at atmospheric pressure.
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity).
27–57	ASTM D–7039	Standard test method for sulfur in gasoline and diesel fuel by monochromatic wavelength dispersive spectrometry.
27–03	ASTM D–4006	Standard test method for water in crude oil by distillation.
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–13	ASTM D–4294	Standard test method for sulfur in Petroleum and Petroleum products by energy dispersive X-ray fluorescence spectrometry.

CBPL No.	ASTM	Title
27–50	ASTM D–93	Standard Test Method for Paraffin-Type for Flash-Point by Pensky-Martens Closed Cup Test.
27–21	ASTM D–4177	Standard Practice for the Automatic Sampling of Petroleum and Petroleum Products.
27–20	ASTM D–4057	Standard Practice for the Manual Sampling of Petroleum and Petroleum Products.
27–58	ASTM D–5191	Standard Test Method for Vapor Pressure of Petroleum Products(Mini Method).
27–16	ASTM E–300	Standard Practice for Sampling Industrial Chemicals.
27–05	ASTM D–4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: February 3, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02793 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval Of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Inspectorate America Corporation has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 25, 2013.

DATES: *Effective Dates:* The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on September 25, 2013. The next triennial inspection date will be scheduled for September 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Inspectorate America Corporation, 3773 Pacheco Blvd., Martinez, CA 94553, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Inspectorate America Corporation is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
2	Tank calibration.
4	Proving systems.
5	Metering.
6	Metering assemblies.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Inspectorate America Corporation is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	ASTM D 287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	ASTM D 4006	Standard test method for water in crude oil by distillation.
27–05	ASTM D 4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	ASTM D 473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	ASTM D 86	Standard Test Method for Distillation of Petroleum Products at Atmoshpheric Pressure.
27–13	ASTM D 4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02797 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Chem Coast, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Chem Coast, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Chem Coast, Inc., has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of August 22, 2013.

DATES: *Effective Dates:* The accreditation and approval of Chem Coast, Inc., as commercial gauger and laboratory became effective on August 22, 2013. The next triennial inspection date will be scheduled for August 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Chem Coast, Inc., 11820 North H Street, Laporte, TX 77571, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Chem Coast, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

Chapters	Title
3	Tank Gauging.
5	Metering.
7	Temperature Determination.
8	Sampling.
12	Calculations of Petroleum Quantities.
17	Marine Measurements.

Chem Coast, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–01	ASTM D–287	Standard test method for API Gravity of crude petroleum products and petroleum products (Hydrometer method).
27–08	ASTM D–86	Standard test method for distillation of petroleum products at atmospheric pressure.
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations for dynamic viscosity).
27–05	ASTM D–4928	Standard test method of water in crude oils by Karl Fisher Titration.
27–50	ASTM D–93	Standard test method for flash point by Penske-Martens Closed Cup Tester.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02802 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek Usa Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, Intertek USA Inc., has been approved to gauge petroleum and certain petroleum products and accredited to test

petroleum and certain petroleum products for customs purposes for the next three years as of May 24, 2012.

DATES: *Effective Dates:* The accreditation and approval of Intertek USA Inc., as commercial gauger and laboratory became effective on May 24, 2012. The next triennial inspection date will be scheduled for May 2015.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA Inc., 4951A East Adamo Drive, Suite 130

Tampa, FL 33605, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Intertek USA Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
9	Density Determination.
12	Calculations.
17	Maritime measurement.

Intertek USA Inc. is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–02	ASTM D 1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–06	ASTM D 473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	ASTM D 86	Standard Test Method for Distillation of Petroleum Products at Atmoshpheric Pressure.
27–11	ASTM D 445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (the Calculation of Dynamic Velocity).
27–13	ASTM D 4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–48	ASTM D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–54	ASTM D 1796	Standard test method for water and sediment in fuel oils by the centrifuge method (Laboratory procedure).
27–57	ASTM D 7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	ASTM D 5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf.*

Dated: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02791 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt, LP as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt, LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt, LP, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 25, 2013.

DATES: *Effective Dates:* The accreditation and approval of Saybolt, LP, as commercial gauger and laboratory became effective on September 25, 2013. The next triennial inspection date will be scheduled for September 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt, LP, 4871 Sunrise Dr., Suite 102, Martinez, CA 94553, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt, LP, is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
2	Tank Gauging.
4	Proving Systems.
5	Metering.
6	Metering Assemblies.
7	Temperature Determination.
8	Sampling.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

Saybolt, LP is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method)
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fisher Titration
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02804 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of AmSpec Services, LLC, as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products for customs purposes for the next three years as of May 30, 2013.

DATES: *Effective Dates:* The accreditation and approval of AmSpec Services, LLC, as commercial gauger became effective on May 30, 2013. The next triennial inspection date will be scheduled for May 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that AmSpec Services, LLC, LPG Division, 11725 Port Rd, Seabrook, TX 77586, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
Chapter 3	Tank Gauging.
Chapter 7	Temperature determination.
Chapter 8	Sampling.
Chapter 11.1	Temperature and Pressure Volume Correction Factors for Generalized Crude Oils, Refined Products, and Lubricating Oils.
Chapter 12	Calculations.
Chapter 17.1	Maritime measurement (LPG).

Anyone wishing to employ this entity to gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger services this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02806 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec Services, LLC, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of June 13, 2013.

DATES: *Effective Dates:* The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on June 13, 2013. The next triennial inspection date will be scheduled for June 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania

Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec Services, LLC, 2310 Highway 69 North, Nederland, TX 77627, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

AmSpec Services, LLC is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–13	ASTM D–4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–08	ASTM D–86	Standard test method for distillation of petroleum products at atmospheric pressure.
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity).
27–54	ASTM D–1796	Standard test method for water and sediment in fuel oils by the centrifuge method (Laboratory procedure).
27–06	ASTM D–473	Standard test method for sediment in crude oils and fuel oils by the extraction method.
27–50	ASTM D–93	Standard test methods for flash point by Penske-Martens Closed Cup Tester.
27–01	ASTM D–287	Standard test method for API gravity of crude petroleum and petroleum products (hydrometer method).
27–03	ASTM D–4006	Standard test method for water in crude oil by distillation.
27–46	ASTM D–5002	Standard test method for density and relative density of crude oils by digital density analyzer.
27–05	ASTM D–4928	Standard test method for water in crude oils by Coulometric Karl Fischer Titration.
27–58	ASTM D–5191	Standard test method for vapor pressure of petroleum products (mini-method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02803 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Marine Technical Surveyors, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Marine Technical Surveyors, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Marine Technical Surveyors, Inc., has been approved to gauge petroleum and certain petroleum products for customs purposes for the next three years as of May 2, 2012.

DATES: *Effective Dates:* The approval of Marine Technical Surveyors, Inc., as commercial gauger became effective on May 2, 2012. The next triennial inspection date will be scheduled for May 2015.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Marine Technical Surveyors, Inc., 2382 Highway 1 South, Donaldsonville, LA 70346, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Marine Technical Surveyors, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service

requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf

Dated: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02800 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of American Cargo Assurance, as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of American Cargo Assurance, as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that American Cargo Assurance, has been approved to gauge petroleum and petroleum products for customs purposes for the next three years as of August 29, 2013.

DATES: *Effective Dates:* The approval of American Cargo Assurance, as commercial gauger became effective on August 29, 2013. The next triennial inspection date will be scheduled for August 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that American Cargo Assurance, 1404–B South Houston Road, Pasadena, TX 77502, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. American Cargo Assurance is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf.

Dated: January 27, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02792 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Approval of Intertek USA, Inc., as a Commercial Gauger.

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Intertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge petroleum and certain petroleum products for customs purposes for the next three years as of January 24, 2013.

DATES: *Effective Dates:* The approval of Intertek USA, Inc., as commercial gauger became effective on January 24, 2013. The next triennial inspection date will be scheduled for January 2016.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Intertek USA, Inc., 214 N Gulf Blvd., Freeport, TX 77541, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Intertek USA, Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dates: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02795 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Intertek USA Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Intertek USA Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA Inc., has been approved to gauge petroleum and certain petroleum

products for customs purposes for the next three years as of July 17, 2012.

DATES: *Effective Dates:* The approval of Intertek USA Inc., as commercial gauger became effective on July 17, 2012. The next triennial inspection date will be scheduled for July 2015.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Intertek USA Inc., 354 Fairbanks Street, Valdez, AK 99686, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Intertek USA Inc. is approved for the following gauging procedures for petroleum and certain petroleum products per the American Petroleum Institute (API) Measurement Standards:

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf*

Dated: January 23, 2014.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2014–02796 Filed 2–7–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2013–N137; FXES111 30600000–145–FF06E00000]

Endangered and Threatened Wildlife and Plants; Draft Revised Recovery Plan for Wyoming Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability for review and comment.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces the availability of a draft revised recovery plan for the Wyoming toad (*Bufo hemiophrys baxteri* now known as *Anaxyrus baxteri*). This species is federally listed as endangered under the Endangered Species Act of 1973, as amended (Act). The Service solicits review and comment from the public on this draft revised plan.

DATES: Comments on the draft revised recovery plan must be received on or before April 11, 2014.

ADDRESSES: Copies of the draft revised recovery plan are available by request from the Wyoming Field Office, U.S. Fish and Wildlife Service, 5353 Yellowstone Road, Suite 308A, Cheyenne, WY 82009; telephone 307–772–2374. Submit comments on the draft recovery plan to the Project Leader at this same address. An electronic copy of the draft recovery plan is available at *http://www.fws.gov/endangered/species/recovery-plans.html*.

FOR FURTHER INFORMATION CONTACT: Project Leader, at the above address, or telephone 307–772–2374 x231.

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the Service's endangered species program. To help guide the recovery effort, the Service prepares recovery plans for the federally listed species native to the United States where a plan will promote the conservation of the species. Recovery plans describe site-specific actions necessary for the conservation of the species, establish objective, measurable criteria which, when met, would result in a determination that the species no longer needs the protection of the Act (16 U.S.C. 1531 *et seq.*), and provide estimates of the time and cost for implementing the needed recovery measures.

The Act requires recovery plans for listed species unless such a plan would not promote the conservation of a particular species. The original plan for the species was approved in 1993. Section 4(f) of the Act, as amended in 1988, requires that public notice and opportunity for public review and comment be provided during recovery plan development. The Service will consider all information received during a public comment period when preparing each new or revised recovery plan for approval. The Service and other Federal agencies also will take these comments into consideration in the course of implementing approved recovery plans. It is our policy to request peer review of recovery plans. We will summarize and respond to the issues raised by the public and peer reviewers in an appendix to the approved recovery plan.

The Wyoming toad (*Bufo hemiophrys baxteri* now known as *Anaxyrus baxteri*), a glacial relict species found only in Albany County, Wyoming, was listed as an endangered species on January 17, 1984 (49 FR 1992). The Wyoming toad is considered one of the four most endangered amphibian species in North America and is classified as "extinct in the wild" (IUCN 2013). Approximately 500 individuals are in captivity.

Recovery of this species will require both sustained, long-term conservation actions and repeated experimentation to determine the optimal means to reestablish wild populations. The known historic distribution of the Wyoming toad was restricted to approximately 5,000 hectares (50 sq. km) of habitat, consisting of flood plains, ponds, and small seepage lakes in the short-grass communities of the Laramie Basin in Albany County, Wyoming. Limiting factors include: (1) Land-use alterations that affect connectivity and the natural form, function, and hydrologic processes of the Laramie River; (2) limited distribution; (3) habitat manipulation; (4) disease; and (5) small population size. The recovery strategy for the Wyoming toad focuses on acquisition of suitable habitat within or nearby the toad's historic range to allow reintroduction into appropriate habitats. Recovery actions are designed to protect the species' habitat and increase the knowledge of the species' genetics, life history, and population dynamics; the relationship of the Wyoming toad to its environment; and its responses to identified threats.

Request for Public Comments

The Service solicits public comments on the draft revised recovery plan. All comments received by the date specified in **DATES** will be considered prior to approval of the plan. Written comments and materials regarding the plan should be addressed to the Field Supervisor (see **ADDRESSES** section). Comments and materials received will be available, by appointment, for public inspection during normal business hours at the above address. All public comment information provided voluntarily by mail or by phone becomes part of the official public record. If requested under the Freedom of Information Act by a private citizen or organization, the Service may provide copies of such information.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: January 16, 2014.

Matt Hogan,

Deputy Regional Director, Denver, Colorado.

[FR Doc. 2014–02779 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTL060–L16100000–DO0000]

Notice of Intent To Prepare a Resource Management Plan and Associated Environmental Impact Statement for the Lewistown Field Office and a Portion of the Butte Field Office, Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) Lewistown and Butte Field Offices intend to prepare a Resource Management Plan (RMP) with an associated Environmental Impact Statement (EIS) for the RMP for BLM public lands and resources managed by the Lewistown Field Office, and a small portion of the Butte Field Office in northern Lewis and Clark County, Montana. Through this notice, public scoping is also being announced to solicit public comments and assist with the identification and development of planning issues. The RMP will replace the existing Headwaters Resource Area RMP, dated September 1984, and the Judith Resource Management Plan, dated 1994, as amended.

DATES: This notice initiates the public scoping process for the RMP and associated EIS. Comments and resource information should be submitted to the BLM within 60 calendar days of publication of this notice in the **Federal Register**. A series of public scoping meetings will be held throughout the planning area. Meeting times and locations will be announced 15 days prior to each event through local news media, newsletters and the BLM Web site at: *http://blm.gov/ngld.*

Formal scoping comments should be submitted prior to the close of the scoping period or 30 days after the last public scoping meeting, whichever is later. The BLM will provide additional opportunities for public participation upon publication of the Draft RMP/EIS.

ADDRESSES: Documents related to this proposal may be viewed at the Lewistown Field Office, 920 NE Main St., Lewistown, MT 59457, during regular business hours from 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays, or online at: *http://blm.gov/ngld.* Written public comments and input may be submitted by any of the following methods:

- Email: blm_mt_lewistown_rmp@blm.gov
- Fax: 406–538–1904, Attention: Lewistown RMP
- Mail: BLM Lewistown Field Office, Attention:

Lewistown RMP, 920 NE Main St., Lewistown, MT 59457

FOR FURTHER INFORMATION CONTACT: Dan Brunkhorst, RMP Project Manager, Lewistown Field Office, at 406–538–1981 or by email blm_mt_lewistown_rmp@blm.gov. Contact Mr. Brunkhorst if you wish to be added to the mailing list.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM intends to prepare an RMP with an associated EIS, for the Lewistown Field Office and a portion of the Butte Field Office for public lands located in northern Lewis and Clark County. This notice also announces the beginning of the scoping process and seeks public input on issues, planning criteria, and nominations for Areas of Critical Environmental Concern (ACEC).

The RMP/EIS will fulfill the needs and obligations set forth by FLPMA, NEPA, and BLM management policies. The area to be covered under the Lewistown RMP/EIS is located in the central part of Montana in Petroleum, Fergus, Judith Basin, Chouteau, Cascade, Meagher, Teton, Pondera, and northern Lewis and Clark counties. The Lewistown RMP planning area comprises approximately 654,025 acres of BLM-managed surface lands and 1,399,880 acres of BLM-administered Federal minerals.

The BLM will work collaboratively with interested parties and cooperating agencies to identify the management decisions that are best suited to local, regional, tribal and national needs and concerns. The public scoping process will identify, develop, and refine planning issues and planning criteria, including an evaluation of the existing RMP, in the context of the needs and interests of the public. Planning issues and criteria will guide the planning process. Comments on issues and planning criteria may be submitted in writing to the BLM at any public scoping meeting or by using one of the methods listed above.

Preliminary issues, management concerns and planning criteria have been identified by BLM personnel and other agencies. This information represents the BLM's knowledge to date regarding the existing issues and concerns with current land management. The preliminary issues that will be addressed in this planning effort include:

- Vegetation management (including noxious weeds and invasive species management);
- Fish and wildlife habitat;
- Special status species;
- Recreation and visitor services;
- Forest management;
- Fire management (including issues related to the wildland urban interface);
- Livestock grazing;
- Land tenure adjustment;
- Right-of-way corridors and land use authorizations;
- Minerals and energy development;
- Recreation management (including commercial special recreation permits);
- Travel management and access;
- Opportunities to identify areas for regional mitigation strategies; and
- Special management area designations, (including nominations for ACECs and comments specific to existing ACECs and other special designation areas).

After public comments are gathered regarding issues the RMP/EIS should address, they will be placed in one of three categories:

1. Issues to be resolved in the RMP/EIS;

2. Issues to be resolved through policy or administrative action; or

3. Issues beyond the scope of the RMP/EIS.

Rationale will be provided in the RMP/EIS for each comment placed in category two or three. In addition to

these major issues, a number of management questions and concerns will be addressed in the RMP/EIS. The public is encouraged to help identify these questions and concerns during the scoping phase.

The BLM will use an interdisciplinary approach to develop the RMP/EIS in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process, including but not limited to: Rangeland management; minerals and geology; wildland fire and fuels management; outdoor recreation; archaeology; paleontology; wildlife and fisheries; lands and realty; soil, water and air; global climate change; environmental justice, sociology, and economics.

The following preliminary planning criteria have been proposed to guide development of the RMP/EIS, avoid unnecessary data collection and analyses, and ensure the RMP/EIS is tailored to the issues. Other criteria may be identified during the public scoping process. After gathering comments on preliminary planning criteria, the BLM will finalize the criteria and provide feedback to the public on the criteria to be used throughout the planning process. Some of the planning criteria that are under consideration include:

- The plan will be completed in compliance with FLPMA and all other applicable laws.
- The planning process will include an EIS that will comply with NEPA.
- The plan will establish new guidance and identify existing guidance upon which the BLM will rely in managing public lands within the Lewistown Field Office and the Butte Field Office (for the northern portion of Lewis and Clark County).
- The RMP/EIS will incorporate by reference the *Standards for Rangeland Health and Guidelines for Livestock Grazing Management;* the *Off-Highway Vehicle EIS and Plan Amendment for Montana, North Dakota, and Portions of South Dakota;* the *Montana/Dakotas Statewide Fire Management Plan; Best Management Practices for Forestry in Montana;* the *Montana Streamside Management Zone Law and Rules,* and the *Vegetation Treatments Using Herbicides Final EIS.*
- The RMP/EIS will incorporate by reference all prior Wilderness Study Area findings that affect public lands in the planning area.
- The planning process will include early coordination and Endangered Species Act (ESA) consultation meetings with the U.S. Fish and Wildlife Service during the development of the plan.
- Native American consultation and coordination—the Blackfeet Indian Reservation is adjacent to the planning area (Pondera County). Also, other tribes will be contacted early during the scoping process to determine what level of participation they would like to have during the RMP process. Early consultation and close coordination will take place to ensure the tribes' needs are considered, analyzed, and the BLM fulfills its trust responsibilities.
- Early consultation will be conducted with the State Historic Preservation Office (SHPO) on any potential effect of the plan on cultural resources under provisions of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470f) and under the National Programmatic Agreement. Relevant/interested tribal governments and the SHPO will be invited as cooperating agencies.
- The plan will result in determinations as required by special program and resource specific guidance as described in BLM Manual 6280—Management of National Scenic and Historic Trails and Trails under Study or Recommended as Suitable for Congressional Designation.
- The plan will be consistent with BLM Handbook H–1624–1, *Planning for Fluid Minerals* (and/or updated manual/policy guidance).
- The RMP/EIS will be consistent with the interagency reference guide titled *Reasonably Foreseeable Development Scenarios and Cumulative Effects Analysis* developed by the Rocky Mountain Federal Leadership Forum on NEPA, Oil and Gas, and Air Quality.
- The plan will recognize the State's responsibility to manage wildlife populations, including uses such as hunting and fishing, within the planning area.
- To the extent possible, goals and objectives in the plan for plants and wildlife (including special status species) will incorporate or respond to goals and objectives from established recovery plans, conservation strategies, strategic plans, etc.
- Decisions in the plan will strive to be compatible with the existing plans and policies of adjacent local, State, tribal, and Federal agencies as long as the decisions are in conformance with legal mandates on management of public lands.
- The scope of analysis will be consistent with the level of analysis in approved plans and in accordance with Bureau-wide standards and program guidance.
- Geospatial data will be automated within a Geographic Information System to facilitate discussions of the affected environment, alternative formulation, analysis of environmental consequences, and display of the results.
- Resource allocations must be reasonable and achievable within available technological and budgetary constraints.
- Best management practices (BMPs) for oil and gas, road drainage, grazing, water quality BMPs for Montana forests, fire rehab, fire management, wind energy, power lines, and sage grouse conservation will be included in the Plan.
- The BLM will coordinate with the Lewis and Clark National Historic Trail, Nez Perce National Historic Trail and the Continental Divide National Scenic Trail Administrators during the land use planning process regarding the establishment of the National Trail Management Corridors.

Respondents' comments, including names and street addresses, will be available for public review at the Lewistown Field Office during regular business hours 8:00 a.m.—4:30 p.m., Monday through Friday, except holidays, and may be published as part of the RMP/EIS. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Formal scoping comments should be submitted within 60 days of publication of this notice in the **Federal Register** or 30 days after the last public scoping meeting, whichever is later. All submissions from organizations and businesses, and from individuals identifying themselves as representatives of organizations or businesses, will be available for public inspection in their entirety.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2

Katherine P. Kitchell,

Acting State Director.

[FR Doc. 2014–02801 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY910000 L16100000 XX0000]

Notice of Public Meeting; Wyoming Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Wyoming Resource Advisory Council (RAC) will meet as indicated below.

DATES: The meeting will be held March 12, 2014 (1 p.m. to 5:20 p.m.), March 13, 2014 (7:30 a.m. to 5:15 p.m.), and March 14, 2014 (8:00 a.m. to noon).

ADDRESSES: The meeting will be held at the Thermopolis Volunteer Fire Department and Hot Springs County Fire District Fire Station, 400 South 14th Street, Thermopolis, Wyoming. The March 13 meeting will begin with a site visit that will leave from the Best Western Plus Plaza Hotel, 116 East Park Street, Thermopolis, Wyoming.

FOR FURTHER INFORMATION CONTACT: Christian Venhuizen, Wyoming Resource Advisory Council Coordinator, Wyoming State Office, 5353 Yellowstone, Cheyenne, WY 82009; telephone 307–775–6103; email *cvenhuizen@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This 10-member RAC advises the Secretary of the Interior on a variety of management issues associated with public land management in Wyoming.

Planned agenda topics include discussions on bentonite mining process and reclamation challenges, enhanced oil recovery, off-site mitigation, cultural resource issues, Native American Graves Protection and Repatriation Act, public participation regarding the National Environmental Policy Act, and follow-up to previous meetings.

On Wednesday, March 12, the meeting will begin at 1:00 p.m. at the Thermopolis Volunteer Fire Department and Hot Springs County Fire District Fire Station. On Thursday, March 13, there will be site visits of the bentonite mining site at Meeteetse Draw, the Wyo-Ben Lucerne Bentonite Plant and Legacy Oil Field. The public may attend the site visits, but they must provide their own transportation. The site visit will leave from the Best Western Plus Plaza Hotel, in Thermopolis, at 7:30 a.m. The meeting will resume at the Thermopolis Volunteer Fire Department and Hot Springs County Fire District Fire Station, at 12:30 p.m. On Friday, March 14, the meeting will begin at 8 a.m. at the Thermopolis Volunteer Fire Department and Hot Springs County Fire District Fire Station.

All RAC meetings are open to the public with time allocated for hearing public comments. On Friday, March 14, there will be public comment period beginning at 8:00 a.m. The public may also submit written comments to the RAC. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. If there are no members of the public interested in speaking, the meeting will move promptly to the next agenda item.

Donald A. Simpson,

State Director.

[FR Doc. 2014–02781 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO600000.L18200000.XH0000]

Call for Nominations for Resource Advisory Councils

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management (BLM) Resource Advisory Councils (RAC) that have member terms expiring this year. The RACs provide advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within their geographic areas. The BLM will accept public nominations for 45 days after the publication of this notice.

DATE: All nominations must be received no later than March 27, 2014.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for the address of BLM State Offices accepting nominations.

FOR FURTHER INFORMATION CONTACT: Lauren Luckey, Department of the Interior, Bureau of Land Management, Correspondence, International, and Advisory Committee Office, 1849 C Street NW., MS–MIB 5070, Washington, DC 20240; 202–208–3806.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM. Section 309 of FLPMA (43 U.S.C. 1739) directs the Secretary to establish 10- to 15-member citizen-based advisory councils that are consistent with the Federal Advisory Committee Act (FACA). As required by FACA, RAC membership must be balanced and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR subpart 1784 and include the following three membership categories:

Category One—Holders of Federal grazing permits and representatives of organizations associated with energy and mineral development, timber industry, transportation or rights-of-way, developed outdoor recreation, off-highway vehicle use, and commercial recreation;

Category Two—Representatives of nationally or regionally recognized environmental organizations, archaeological and historic organizations, dispersed recreation activities, and wild horse and burro organizations; and

Category Three—Representatives of State, county, or local elected office, employees of a state agency responsible for management of natural resources, representatives of Indian tribes within or adjacent to the area for which the council is organized, representatives of academia who are employed in natural sciences, and the public-at-large.

Individuals may nominate themselves or others. Nominees must be residents of the state in which the RAC has jurisdiction. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographical area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making. The Obama Administration prohibits individuals who are currently federally registered lobbyists from being appointed or re-appointed to FACA and non-FACA boards, committees, or councils.

The following must accompany all nominations:

—Letters of reference from represented interests or organizations;
—A completed Resource Advisory Council application; and
—Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, BLM state offices will issue press releases providing additional information for submitting nominations, with specifics about the number and categories of member positions available for each RAC in the state. Nominations and completed applications for RACs should be sent to the appropriate BLM offices listed below:

Alaska

Alaska RAC

Thom Jennings, Alaska State Office, BLM, 222 West 7th Avenue, #13, Anchorage, Alaska 99513, 907–271–3335.

Arizona

Arizona RAC

Dorothea Boothe, Arizona State Office, BLM, One North Central Avenue, Suite 800, Phoenix, Arizona 85004, 602–417–9219.

California

Central California RAC

David Christy, Mother Lode Field Office, BLM, 5152 Hillsdale Circle, El Dorado Hills, California 95762, 916–941–3146.

Colorado

Front Range RAC

Kyle Sullivan, Royal Gorge Field Office, BLM, 3028 East Main Street, Cañon City, Colorado 81212, 719–269–8553.

Northwest RAC

David Boyd, Colorado River Valley Field Office, BLM, 2300 River Frontage Road, Silt, Colorado 81652, 970- 876–9008.

Southwest RAC

Shannon Borders, Southwest District Office, BLM, 2465 South Townsend Avenue, Montrose, Colorado 81401, 970–240–5399.

Idaho

Boise District RAC

Marsh Buchanan, Boise District Office, BLM, 3948 Development Avenue, Boise, Idaho 83705, 208–384–3393.

Coeur d'Alene District RAC

Suzanne Endsley, Coeur d'Alene District Office, BLM, 3815 Schreiber Way, Coeur d'Alene, Idaho 83815, 208–769–5004.

Idaho Falls District RAC

Sarah Wheeler, Idaho Falls District Office, BLM, 1405 Hollipark Drive, Idaho Falls, Idaho 83401, 208–524–7613.

Twin Falls District RAC

Heather Tiel-Nelson, Twin Falls District Office, BLM, 2536 Kimberly Road, Twin Falls, Idaho 83301, 208–736–2352.

Montana and Dakotas

Central Montana RAC

Jonathan Moor, Lewistown Field Office, BLM, 920 Northeast Main Street, Lewistown, Montana 59457, 406–538–1943.

Dakotas RAC

Mark Jacobsen, Miles City Field Office, BLM, 111 Garryowen Road, Miles City, Montana 59301, 406–233–2800.

Eastern Montana RAC

Mark Jacobsen, Miles City Field Office, BLM, 111 Garryowen Road, Miles City, Montana 59301, 406–233–2800.

Western Montana RAC

David Abrams, Butte Field Office, BLM, 106 North Parkmont, Butte, Montana 59701, 406–533–7617.

Nevada

Mojave-Southern Great Basin RAC; Northeastern Great Basin RAC; Sierra Front Northwestern Great Basin RAC

Chris Rose, Nevada State Office, BLM, 1340 Financial Boulevard, Reno, Nevada 89502, 775–861–6480.

New Mexico

Albuquerque District RAC

Chip Kimball, Albuquerque District Office, BLM, 435 Montano NE., Albuquerque, New Mexico 87107, 505–761–8734.

Farmington District RAC

Christine Horton, Farmington District Office, BLM, 6251 College Boulevard, Farmington, New Mexico 87402, 505–564–7633.

Las Cruces District RAC

Rena Gutierrez, Las Cruces District Office, BLM, 1800 Marquess St., Las Cruces, New Mexico 88005, 575–525–4338.

Pecos District RAC

Howard Parman, Pecos District Office, BLM, 2909 West Second Street, Roswell, New Mexico 88201, 575–627–0212.

Oregon/Washington

Eastern Washington RAC; John Day-Snake RAC; Southeast Oregon RAC

Stephen Baker, Oregon State Office, BLM, 333 SW First Avenue, P.O. Box 2965, Portland, Oregon 97204, 503–808–6306.

Utah

Utah RAC

Sherry Foot, Utah State Office, BLM, 440 West 200 South, Suite 500, P.O. Box 45155, Salt Lake City, Utah 84101, 801–539–4195.

Authority: 43 CFR 1784.4–1

Dated: February 3, 2014.

Steve Ellis,

Acting Deputy Director.

[FR Doc. 2014–02851 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF INTERIOR

National Park Service

[NPS–WASO–NRSS–SSD–14980; PPWONRADE3, PPMRSNR1Y.NM0000]

Proposed Information Collection; National Park Service Visitor Survey Card

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on May 31, 2014. We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that your comments on this IC are considered, we must receive them on or before April 11, 2014.

ADDRESSES: Direct all written comments on this IC to Phadrea Ponds, Information Collection Coordinator, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525 (mail); or *phadrea_ponds@nps.gov* (email). Please reference Information Collection 1024–0216–VSC in the subject line.

FOR FURTHER INFORMATION CONTACT: Bret Meldrum, Chief, Social Science

Program, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525–5596 (mail); *Bret_Meldrum@nps.gov* (email); or 970–267–7295 (phone).

I. Abstract

The Visitor Survey Card (VSC) is used to measures visitors' opinions about park facilities, services, and recreational opportunities in each park unit and System-wide. In addition, the survey collects data strategic planning goal that contribute to NPS and DOI performance reports. Results of the VSC will also be used by park managers to improve visitor services at the approximately 330 units of the National Park System where the survey is administered.

II. Data

OMB Number: 1024–0216.

Title: National Park Service Visitor Survey Card.

Service Form Number(s): None.

Type of Request: Renewal of a previously approved collection.

Description of Respondents: Individuals or households; visitors to approximately 330 NPS units.

Respondent's Obligation: Voluntary.

Estimated Number of Annual Respondents: 40,000 respondents.

Estimated Time and Frequency of Response: This is a one-time survey estimated to take 3 minutes per respondent to complete.

Estimated Total Annual Burden Hours: 2,000 hours.

Estimated Annual "Non-Hour Cost" Burden: We have not identified any "non-hour cost" burdens associated with this collection of information.

III. Request for Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: February 4, 2014.

Madonna L. Baucum,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2014–02777 Filed 2–7–14; 8:45 am]

BILLING CODE 4310–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–14821; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 11, 2014. Pursuant to section 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2014. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 13, 2014.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

CALIFORNIA

Contra Costa County

Memorial Hall, Pomona St. at Alexander Ave., Crockett, 14000013

DISTRICT OF COLUMBIA

District of Columbia

Park View Playground and Field House, 693 Otis Pl. NW., Washington, 14000014

Webster, Marjorie, Junior College Historic District, 1638 & 1640 Kalmia Rd. NW., 7753 & 7775 17th St. NW., Washington, 14000015

KENTUCKY

Fayette County

Fayette National Bank (Boundary Increase), 167 W. Main St., Lexington, 14000016

Garrard County

Paint Lick Commercial District, Roughly along Richmond Rd., Paint Lick, 14000017

MASSACHUSETTS

Barnstable County

Hatch, Ruth and Robert Jr., House, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 309 Bound Brook Way, Wellfleet, 14000018

Kugel, Peter, House, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 188 Long Pond Rd., Wellfleet, 14000019

Kuhn, Samuel and Minette, House, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 420 Griffins Island Rd., Wellfleet, 14000020

Sirna, Anthony and Allison, Studio, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 60 Way #4, Wellfleet, 14000021

Tiszl, Vera and Lazlo, House, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 2 Deer Trail, Wellfleet, 14000022

Weidlinger, Paul and Madeleine, (Mid 20th Century Modern Residential Architecture on Outer Cape Cod MPS) 54 Valley Rd., Wellfleet, 14000023

MICHIGAN

Wayne County

Redstone, Louis G., Residential Historic District, 19303, 19309 & 19315 Appoline St., Detroit, 14000024

NEW MEXICO

Eddy County

Caverns, The, Historic District (Boundary Increase), At end of NM 7, Carlsbad, 14000012

NEW YORK

Monroe County

Oatka Cemetery, 411 Scottsville-Mumford Rd., Wheatland, 14000025

New York County

South Village Historic District, Roughly Bedford, Carmine, Downing, Grand, Jones, Leroy, MacDougal, Prince, W. 3rd, W. Houston Sts., LaGuardia Pl., Manhattan, 14000026

OHIO

Butler County

Main Street Commercial Historic District, Jct. of Main St. & Central Ave., Middletown, 14000027

Cuyahoga County

Tower East, 20600 Chagrin Blvd., Shaker Heights, 14000029

Pickaway County

Bulen, Granville M., House and Farm Complex, 10001 Bulen-Pierce Rd., Lockbourne, 14000028

Summit County

Goodyear Hall—Ohio Savings and Trust Company, 1201 E. Market St., Akron, 14000030

SOUTH DAKOTA

Faulk County

Sievers School, (Schools in South Dakota MPS) NE. corner of 362nd Ave. & 170th St., Rockham, 14000031

Lyman County

Iron Nation's Gravesite, Messiah Cemetery, Iron Nation District, Lower Brule Sioux Reservation, Lower Brule, 14000032

Miner County

Nansen Store, 43713 228th St., Howard, 14000033

[FR Doc. 2014–02751 Filed 2–7–14; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–14911: PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 18, 2014. Pursuant to § 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2014. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 27, 2014.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

CALIFORNIA

Los Angeles County

Lasky—DeMille Barn, 2100 N. Highland St., Los Angeles, 14000034

GUAM

Guam County

Dislocated Latte from Fena at Senator Angel L.G. Santos Latte Park, Address Restricted, Hagatna, 14000036

Fonte River Dam, Across Fonte R., Libugon, 14000035

Lumuna Shell Trumpet, 238 Archbishop Flores St., Hagatna, 14000037

Yokoi, Sergeant Shoichi, Collection, 238 Archbishop Flores St., Hagatna, 14000038

MINNESOTA

Ramsey County

St. Paul Union Depot (Boundary Increase), (Railroads in Minnesota MPS) 214 E. 4th St., St. Paul, 14000039

OHIO

Clark County

Wittenberg University Historic District, Roughly bounded by Bill Edwards Dr., N. Fountain, W. Ward & Plum, Springfield, 14000040

Franklin County

High and Gay Streets Historic District, Bounded by Gay, Wall & High Sts., Pearl, Lynn & Elm Alleys, Columbus, 14000041

Lake County

Staley, Mr. and Mrs. Karl A., House, 6363 Lake Rd., W., Madison, 14000042

SOUTH CAROLINA

Chesterfield County

Smalls, Robert, School, 316 Front St., Cheraw, 14000043

VERMONT

Orange County

Fairlee Town Hall, 75 Town Common Rd., Fairlee, 14000044

[FR Doc. 2014–02750 Filed 2–7–14; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–739]

Certain Ground Fault Circuit Interrupters and Products Containing Same

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute an advisory opinion proceeding in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Clark S. Cheney, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2661. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 8, 2010, based on a complaint filed by Leviton Manufacturing Co., Inc. of Melville, New York ("Leviton"). 75 FR 62420 (Oct. 8, 2010). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain ground fault circuit interrupters ("GFCIs") and products containing the same by reason of infringement of, inter alia, U.S. Patent No. 7,737,809 ("the '809 patent"). In the course of proceedings, the Commission entered cease and desist orders against numerous defaulting foreign and domestic respondents, including Menard, Inc. of Eau Claire, Wisconsin. In connection with briefing to the Commission on remedy and the public interest, non-party Pass & Seymour, Inc. of Syracuse, New York ("P&S") argued

for a carve-out for P&S GFCIs from any general exclusion order. P&S argued that Leviton deliberately avoided naming P&S as a respondent or accusing P&S's products, and that any exclusion order ought not reach P&S's products. The Commission rejected P&S's argument, and issued a general exclusion order, but invited P&S to "avail itself of other Commission procedures to obtain a ruling as to whether its products are subject to the general exclusion order." Comm'n Op. 91–92 (Apr. 27, 2012).

On August 29, 2012, Leviton filed a complaint for enforcement proceedings under Commission rule 210.75(b). Among Leviton's allegations was that Menard violated the cease and desist order by selling P&S GFCIs. *See* Enforcement Compl. ¶¶ 64–67. On November 1, 2012, the Commission instituted the enforcement proceeding sought by Leviton. 77 FR 66080 (Nov. 1, 2012). On November 2, 2012, P&S moved to intervene as a respondent, and on November 27, 2012, the ALJ substantially granted that motion. Order No. 71 at 4–5 (Nov. 27, 2012) (granting motion to intervene, but limiting P&S's participation to issues of infringement and remedy). Leviton subsequently entered a Settlement and License Agreement with P&S, and Menard and P&S were terminated from the enforcement proceeding. Order No. 76 (Feb. 4, 2013), *not reviewed,* Notice (Mar. 1, 2013).

On November 20, 2013, P&S filed a request with the Commission for an advisory opinion pursuant to Commission rule 210.79, with regard to certain redesigned P&S products. On December 2, 2013, Leviton opposed. On December 16, 2013, P&S moved for leave to file a reply, which P&S appended to its motion. The Commission has determined to grant P&S's motion for leave to file the reply.

Upon consideration of this matter, the Commission has determined to institute an advisory opinion proceeding under Commission rule 210.79 and has issued an order concerning the scope of that proceeding. The Commission has referred P&S's request to the Chief Administrative Law Judge to designate a presiding administrative law judge for the proceedings. The following entities are named as parties to the proceeding: (1) Complainant Leviton; (2) respondent P&S; and (3) the Office of Unfair Import Investigations.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 4, 2014.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2014–02729 Filed 2–7–14; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Committee on Rules of Practice and Procedure

AGENCY: Judicial Conference of the United States Advisory Committee on Rules of Evidence.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Evidence will hold a one-day meeting. The meeting will be open to public observation but not participation.

DATES: April 4, 2014.

TIME: 8:30 a.m. to 5:00 p.m.

ADDRESSES: University of Maine School of Law, 246 Deering Avenue, Portland, Maine 04102.

FOR FURTHER INFORMATION CONTACT: Jonathan C. Rose, Secretary and Chief Rules Officer, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: February 4, 2014.

Jonathan C. Rose,

Secretary and Chief Rules Officer.

[FR Doc. 2014–02730 Filed 2–7–14; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On January 29, 2014 the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Central District of California in the lawsuit entitled *United States* v. *Mitchell Rubber Products, Inc.*, Civil Action No. 14-cv-00708–ABC–MAN.

The Consent Decree resolves claims under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9607 related to releases and threatened releases of hazardous substances at the Puente Valley Operable Unit ("PVOU") of the San Gabriel Valley Superfund Site, Area 4, Los Angeles County, California (the "Site"). The Consent Decree resolves a claim against Mitchell Rubber Products, Inc., ("Mitchell"), and recovers $434,000 in response costs. The Consent Decree contains a covenant not to sue for past and certain future costs and response work at the Site under Sections 106 and 107 of CERCLA and Section 7003 of RCRA.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Mitchell Rubber Products, Inc.*, D.J. Ref. No. 90–11–2–354/34. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail ..	*pubcomment-ees.enrd@usdoj.gov*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Under section 7003(d) of RCRA, a commenter may request an opportunity for a public meeting in the affected area.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to:

Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $8.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014–02824 Filed 2–7–14; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On January 31, 2014, the Department of Justice lodged a proposed a Consent

Decree with the United States District Court for the Southern District of Ohio in the lawsuit entitled *United States* v. *3M Company, et al.*, Civil Action No. 3:14-cv-00032–WHR.

The United States filed this lawsuit under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). The United States' complaint requests recovery of costs that the United States incurred responding to releases of hazardous substances at the Lammers Barrel Superfund Site (the "Site") in BeaverCreek, Ohio. The complaint also seeks injunctive relief, specifically, performance of the remedial action for Operable Unit 1 at the Site selected by the United States Environmental Protection Agency ("EPA"). Under the terms of the Consent Decree, the Defendants have agreed to (1) perform the remedial action selected by EPA for Operable Unit 1, at an estimate cost of $3.4 million; (2) implement institutional controls; (3) reimburse the United States $1,496,689.04 for past response costs; (4) reimburse the United States for future response costs.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *3M Company et al.*, D.J. Ref. No. 90–11–3–07706. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail ..	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, D.C. 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to:

Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $89.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the signature pages and Appendices, the cost is $24.25.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014–02831 Filed 2–7–14; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB #1121–NEW]

Agency Information Collection Activities: Proposed collection; Comment Requested; New Collection: Census of Adult Probation Supervising Agencies, 2014

ACTION: 60-Day notice.

The Department of Justice (DOJ), Office of Justice Programs, will be submitting the following information collection to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until April 11, 2014. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially regarding the estimated public burden and associated response time, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Glaze, Statistician, Bureau of Justice Statistics, 810 7th St., NW., Washington, DC 20531 (*email Lauren.Glaze@usdoj.gov; phone* (202) 305–9628).

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses.

Overview of this information collection

(1) *Type of Information Collection:* New Collection. While the Bureau of Justice Statistics conducted a census of probation and parole agencies in 1991, the 2014 Census of Adult Probation Supervising Agencies is now a standalone collection. This collection's scope is narrower and only includes adult probation agencies. The scope of the 1991 census was broader and included both adult probation and parole agencies.

(2) *Title of the Form/Collection:* 2014 Census of Adult Probation Supervising Agencies.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

(a) *Form number:* CAPSA–AIF is the Agency Information Form (AIF) for public agencies, CAPSA–CIF is the Company Information Form (CIF) for private probation companies, CAPSA–1A is the questionnaire for public probation agencies, and CAPSA–1B is the questionnaire for private probation companies. Corrections Statistics Program, Bureau of Justice Statistics, Office of Justice Programs, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract: Primary:* State or local government. *Other:* Federal government or private companies. The primary goals of the work under this clearance are to: 1) enhance and validate a national roster of probation agencies that supervise adults on probation for a felony (or those that supervise felons and misdemeanants) and private companies that directly supervise adult probationers; and 2) collect information from those agencies to report national and state-level statistics that provide a clear understanding of how adult probation in the United States is currently organized, the supervision policies and practices agencies have established to administer adult probation, the various types of functions adult probation agencies perform, and the different types of individuals supervised by adult probation agencies. The Bureau of Justice Statistics will use this information in published reports and for the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, and others

interested in community corrections statistics.

All agencies and companies that are believed to supervise adult probationers are on a preliminary roster that BJS and Westat, the data collection agent for the CAPSA, developed by reviewing and compiling data and information from various available resources. The CAPSA–AIF or CAPSA–CIF will be mailed to the head of each agency/company on the preliminary roster and the head of the agency/company will be asked to confirm the contact information for the agency/company and designate a respondent(s) to complete the CAPSA questionnaire. Agency/company heads will be asked to fax, email, or mail the AIF or CIF to Westat. Designated respondents from public probation agencies will receive the CAPSA–1A questionnaire and will be asked to report via the Internet through a web survey with telephone reporting as a secondary mode. Designated respondents from private probation companies will receive the CAPSA–1B questionnaire and will be asked to return the paper questionnaire by fax, email, or mail. Telephone will also serve as a secondary mode of data collection for private probation companies.

The CAPSA–1A will collect information from public probation agencies about their branch and level of government, the various functions they perform, the policies and practices they have in place to administer adult probation related to both adult probationers and the community corrections officers that supervise them, the extent to which agencies have supervision authority, the various populations they serve, the size of their adult probation population, and funding sources for adult probation. In an effort to validate the roster of probation agencies and companies, respondents will also be asked to review a list of public probation agencies in their state to identify any that may be missing from the list. They will also be asked to report any private probation companies that supervise adult probationers in their state.

The CAPSA–1B will collect information from private probation companies about the various functions they perform, the number of states for which they supervise adult probationers, the branches and levels of government from which they receive adult probationers to supervise, the extent to which any governmental entity conducts oversight of their supervision activities, the various populations they serve, the size of their adult probation population, and the practices and methods they use to administer adult probation.

Both the CAPSA–1A and CAPSA–1B questionnaires will include questions to confirm that the agencies/companies supervise adult probationers and are therefore correctly included on the roster and fall within the scope of the CAPSA.

In addition, because the organization of adult probation varies drastically not only by state but within particular states, as part of the work under this clearance to enhance and validate the roster of adult probation agencies and companies, one informant in each state, the District of Columbia, and the Federal system will be asked to complete a telephone interview. These contacts are necessary to assist in: (1) identifying any agencies that may be missing or should be removed from the roster (e.g., agencies that are no longer in operation); (2) updating information contained in the resources that have been used to develop the preliminary roster since some of the source material was only available from publications that were published 5 to 10 years ago; and (3) resolving questions about how probation is organized in the jurisdiction that stem from differences in the way probation in particular jurisdictions has been described in some of the materials used to develop the preliminary roster.

(5) *An estimate of the total number of respondents and the amount of time needed for an average respondent to respond:*

(a) CAPSA–AIF form: Approximately 2000 respondents, each taking an average 5 minutes to respond.

(b) CAPSA–CIF form: Approximately 200 respondents, each taking an average of 5 minutes to respond.

(c) CAPSA–1A form: Approximately 2,000 respondents, each taking an average of 65 minutes to respond.

(d) CAPSA–1B form: Approximately 200 respondents, each taking an average of 31 minutes to respond.

(e) 52 telephone calls to informants in each jurisdiction, each taking an average of 30 minutes to respond.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,480 annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Avenue, 145 N Street NE., Room 3W–1407B, Washington, DC 20530..

Dated: February 5, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–02767 Filed 2–7–14; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Benefits Timeliness and Quality Review System

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, "Benefits Timeliness and Quality Review System," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq.

DATES: Submit comments on or before March 12, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201307–1205–002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–6881 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authorization for the Benefits Timeliness and Quality Review System. The Secretary of Labor has a legal responsibility under Social Security Act (SSA) section 303(a)(1) to reimburse a State Workforce Agency (SWA) the necessary costs of proper and efficient administration of State unemployment insurance (UI) laws. The Secretary must establish a means of measuring a SWA's proper and efficient administration in order to certify a State payment. The Secretary must ensure, among other duties needed for a subject employer within a State to be allowed to receive offset credit under the Federal Unemployment Tax Act, that a State UI law conforms to Federal law and that the State complies with the law. The Benefits Timeliness and Quality Program is one of the ways in which the ETA collects program operating information to meet this obligation. SSA section 303(a)(6) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0359.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on February 28, 2014. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 16, 2013 (78 FR 42548).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0359. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Benefits Timeliness and Quality Review System.

OMB Control Number: 1205–0359.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 29,196.

Total Estimated Annual Time Burden: 38,692 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: January 30, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–02790 Filed 2–7–14; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Overhead and Gantry Cranes Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, "Overhead and Gantry Cranes Standard," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Submit comments on or before March 12, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201401-1218-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–6881 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authorization for the information collection requirements contained in the Overhead and Gantry Cranes Standard, codified in regulations 29 CFR 1910.179. More specifically, the regulatory provisions specify requirements for (1) marking the rated load of a crane; (2) preparing a certification record to verify the inspection of a crane hook, hoist chain, or rope; and (3) preparing a report of the rated load test for a repaired hook or modified crane. A covered employer must maintain the records and reports

and disclose them upon request. The Occupational Safety and Health Act authorizes this information collection. *See* 29 U.S.C. 655, 657.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0224.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on February 28, 2014. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 14, 2013 (78 FR 68477).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0224. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Overhead and Gantry Cranes Standard.

OMB Control Number: 1218–0224.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 31,495.

Total Estimated Number of Responses: 643,007.

Total Estimated Annual Time Burden: 621,380 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: February 4, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–02763 Filed 2–7–14; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Workforce Information Grant Plan and Annual Performance Report

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, "Workforce Information Grant Plan and Annual Performance Report," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before March 12, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201309-1205-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–6881 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to obtain OMB approval under the PRA for revisions to the Workforce Information Grant Plan and Annual Performance Report information collection. A State is required annually to submit (1) a grant deliverables certification, (2) an economic analysis economic report, and (3) a performance report, as a condition of receiving Workforce Information core products and services reimbursable grants. The Workforce Investment Act authorizes this information collection. *See* Public Law 105–220 section 111(d)(8); 309.

This ICR has been classified as a revision, because of the addition of a new Internet portal that a State may use to make its submission. The ICR revision also provides for the optional use of providing a hyperlink in order for a State to submit a document that is available on the Internet; the current requirement is for the State always to submit the document in a PDF format.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0417. The current

approval is scheduled to expire on July 31, 2014; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 7, 2013 (78 FR 48198).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0417. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Workforce Information Grant Plan and Annual Performance Report.

OMB Control Number: 1205–0417.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 54.

Total Estimated Number of Responses: 216.

Total Estimated Annual Burden Hours: 31,282.

Total Estimated Annual Other Costs Burden: $0.

Dated: January 29, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–02734 Filed 2–7–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Longitudinal Study of Unemployment Insurance Recipients

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the information collection request (ICR) proposal titled, "National Longitudinal Study of Unemployment Insurance Recipients," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before March 12, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201308–1290–001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or email at *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–6881 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov*. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue, NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov*.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The ICR seeks PRA authorization for the DOL to conduct a national longitudinal study of unemployment insurance (UI) recipients that will help policymakers and program administrators gain information about the experiences of UI recipients. The study will examine the extent to which the UI program reduces recipients' financial hardships, the ways in which job search and reemployment expectations change during and after benefit collection, and customer satisfaction levels with the UI program. The study will address research questions in six broad topic areas: (1) adequacy of UI benefits, (2) reemployment expectations, (3) job search, (4) total UI benefit usage, (5) employment outcomes, and (6) UI recipients' satisfaction with the UI program.

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on July 22, 2013 (78 FR 43929).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the ADDRESSES section within 30 days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201308–1290–001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OS.

Title of Collection: National Longitudinal Study of Unemployment Insurance Recipients.

OMB ICR Reference Number: 121308–0190–001.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 2,178.

Total Estimated Number of Responses: 5,695.

Total Estimated Annual Time Burden: 2,373 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: February 4, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–02821 Filed 2–7–14; 8:45 a.m.]

BILLING CODE 4510–23–P

LEGAL SERVICES CORPORATION

Notice and Request for Comments: LSC Merger of Service Areas in Louisiana

AGENCY: Legal Services Corporation.

ACTION: Notice and Request for Comments—LSC merger of the two service areas covering the south-central and southeastern region of Louisiana.

SUMMARY: The Legal Services Corporation (LSC) intends to merge the two service areas that cover the twelve counties of the south-central region of Louisiana (including Baton Rouge) and the ten counties of the southeastern region of the state (including New Orleans). Grants for these individual service areas have been awarded to Southeast Louisiana Legal Services Corporation (SLLSC) since 2011. For 2014, LSC awarded SLLSC three-year grants for these two service areas. LSC intends to merge the two service areas into one service area and to award one grant for the new combined service area. Doing so will harmonize the grant structure with the current delivery model.

DATES: All comments must be received on or before the close of business on March 12, 2014.

ADDRESSES: Written comments may be submitted to LSC by email to *competition@lsc.gov* (this is the preferred option); by submitting a form online at *http://www.lsc.gov/contact-us;* by mail to Legal Services Corporation, 3333 K Street NW., Third Floor, Washington, DC 20007, Attention: Reginald Haley; or by fax to 202–337–6813.

FOR FURTHER INFORMATION CONTACT: Reginald J. Haley, Office of Program Performance, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007; or by email at *haleyr@lsc.gov.*

SUPPLEMENTARY INFORMATION: The mission of LSC is to promote equal access to justice and to provide funding for high-quality civil legal assistance to low-income persons. Pursuant to its statutory authority, LSC designates service areas in U.S. states, territories, possessions, and the District of Columbia for which it provides grants to legal aid programs to provide free civil legal services.

The LSC Act charges LSC with ensuring that "grants and contracts are made so as to provide the most economical and effective delivery of legal assistance to persons in both urban and rural areas." 42 U.S.C. 2996f(a)(3). Merging the two Louisiana service areas will provide an economical and effective delivery approach for serving the legal needs of the low-income population and will harmonize the grant structure with the current delivery model.

LSC provides grants through a competitive bidding process, which is regulated by 45 CFR Part 1634. In 2013, LSC implemented a competitive grants process for 2014 calendar year funding that included, inter alia, these Louisiana service areas. For 2014, LSC awarded SLLSC three-year grants for both of these service areas. LSC intends to merge the two service areas into a single service area and merge the 2014 grants for those service areas into a single grant beginning March 21, 2014.

LSC invites public comment on this decision. Interested parties may submit comments to LSC no later than the close of business on March 12, 2014. More information about LSC can be found at: *http://www.lsc.gov.*

Dated: February 5, 2014.

Atitaya C. Rok,

Staff Attorney.

[FR Doc. 2014–02810 Filed 2–7–14; 8:45 am]

BILLING CODE 7050–01–P

LIBRARY OF CONGRESS

U.S. Copyright Office

[Docket No. 2012–12]

Orphan Works and Mass Digitization; Request for Additional Comments and Announcement of Public Roundtables

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of Inquiry.

SUMMARY: The U.S. Copyright Office will host public roundtable discussions and seeks further comments on potential legislative solutions for orphan works and mass digitization under U.S. copyright law. The meetings and comments will provide an opportunity for interested parties to address new legal developments as well as issues raised by comments provided in response to the Office's previous Notice of Inquiry.

DATES: The public roundtables will be held on March 10, 2014 from 9:00 a.m. to 5:00 p.m. EST and March 11, 2014 from 9:00 a.m. to 5:00 p.m. EST. Written comments must be received no later than 5 p.m. EST on April 14, 2014.

ADDRESSES:

Public Roundtables

The public roundtables will take place in the Copyright Office Hearing Room, LM—408 of the Madison Building of the Library of Congress, 101 Independence Avenue SE., Washington, DC 20559. The Copyright Office strongly prefers that requests for participation be submitted electronically. The agendas and the process for submitting requests to participate in or observe one of these meetings are included on the Copyright Office Web site. If electronic registration is not feasible, please contact the Office at 202–707–1027.

Public Comments

Members of the public will have the opportunity to submit written comments following the public roundtable meetings. The written comments may address topics listed in this Notice of Inquiry as well as respond to any issues raised during the public meetings. All written comments should be submitted electronically. A comment form will be posted on the Copyright Office Web site at *http://copyright.gov/orphan/* no later than March 12, 2014. The Web site interface requires commenting parties to complete a form specifying name and organization, as applicable, and to upload comments as an attachment via a browser button. To meet accessibility standards, commenting parties must upload

comments in a single file not to exceed six megabytes (MB) in one of the following formats: the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file (not a scanned document). The form and face of the comments must include both the name of the submitter and organization. The Office will post the comments publicly on the Office's Web site exactly as they are received, along with names and organizations. If electronic submission of comments is not feasible, please contact the Office at 202–707–1027 for special instructions.

FOR FURTHER INFORMATION CONTACT: Karyn Temple Claggett, Associate Register of Copyrights and Director of Policy and International Affairs, by telephone at 202–707–1027 or by email at *kacl@loc.gov,* or Catherine Rowland, Senior Counsel for Policy and International Affairs, by telephone at 202–707–1027 or by email at *crowland@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Copyright Office is reviewing the issue of orphan works [1] under U.S. copyright law in continuation of its previous work on the subject and to advise Congress on potential legislative solutions. As part of its current review, the Office is considering recent developments in the legal and business environments regarding orphan works in the context of: (1) occasional or isolated uses of orphan works; and (2) mass digitization. In October 2011, the Office published a Preliminary Analysis and Discussion document (the "Analysis") that examined various legal issues involved in mass digitization projects.[2]

Subsequently, to assist with further review of the issue, the Office published a general Notice of Inquiry (the "Notice") seeking comments from the public on both mass digitization and isolated uses of orphan works.[3] The Notice provided background on the Office's previous review of this issue in its January 2006 *Report on Orphan Works* (the "2006 Report"),[4] legislation proposed in 2006 and 2008,[5] the Google Books Search and Hathitrust litigation,[6] the role of the Office and private registries in alleviating the orphan works problem, legal issues in mass digitization, and recent international developments. In 2013, the Office received ninety-one initial comments from various interested parties and eighty-nine reply comments. The Notice, comments, and background materials are available at the Copyright Office Web site. The Office now announces public roundtables and seeks further public comments to discuss new legal developments as well as specific issues raised by earlier public comments as it considers potential legislative recommendations.

Subjects of Comments and Public Roundtables: After reviewing the comments in response to the Copyright Office's prior Notice, the Office is interested in holding public roundtables to further explore the issues surrounding orphan works and mass digitization. The Office will hold the public roundtable discussions over the course of two days. The first day will cover the following topics: (1) The need for legislation in light of recent legal and technological developments; (2) defining a good faith "reasonably diligent search" standard; (3) the role of private and public registries; (4) the types of works subject to any orphan works legislation, including issues related specifically to photographs; and (5) the types of users and uses subject to any orphan works legislation. The second day will include discussions of the following topics: (1) Remedies and procedures regarding orphan works; (2) mass digitization, generally; (3) extended collective licensing and mass digitization; and (4) the structure and mechanics of a possible extended collective licensing system in the United States. Each of these topics is explained in more detail below.

Additionally, the Office invites further written comments regarding the subjects briefly identified above and further explained below, including from parties who did not previously address those subjects, or those who wish to amplify or clarify their earlier comments or respond to issues raised in the public roundtable meetings. A party choosing to respond to this Notice of Inquiry need not address every subject below, but the Office requests that responding parties clearly identify and separately address each subject for which a response is submitted. Commenters may address any or all of the issues identified below, as well as provide information on other aspects of these issues that are relevant to developing potential legislative solutions to the issues of orphan works and mass digitization.

Day One

Session 1: The Need for Legislation in Light of Recent Legal and Technological Developments

The Office's 2006 Report concluded that the orphan works problem was pervasive and provided draft legislative language for congressional consideration. Though several bills were introduced in 2006 and 2008,[7] none of them ultimately were enacted. Since then, high-profile litigation in the United States brought the issue of orphan works back to the fore. In rejecting the proposed settlement agreement in *The Authors Guild, Inc.* v. *Google Inc.* in 2011, the Southern District Court of New York explicitly noted that it is Congress, and not the courts, who should decide how to resolve the issue of orphan works.[8] Recently, the same district court granted summary judgment to Google on copyright infringement claims relating to the Google Books Library Project, concluding that "Google Books provides significant public benefits," and that its book scanning project constitutes fair use under U.S. copyright law.[9] While the court's ruling did find the Google Books mass digitization project to be fair use, it neither indicated how broadly the opinion could be used to justify other types of mass digitization projects nor did it explicitly address the issue of orphan works.

Similarly, on October 10, 2012, the Southern District of New York also

[1] "An 'orphan work' is an original work of authorship for which a good faith, prospective user cannot readily identify and/or locate the copyright owner(s) in a situation where permission from the copyright owner(s) is necessary as a matter of law." Copyright Office Notice of Inquiry, Orphan Works and Mass Digitization, 77 FR 64555 (Oct. 22, 2012), *available at http://www.copyright.gov/fedreg/2012/77fr64555.pdf.*

[2] U.S. Copyright Office, Legal Issues in Mass Digitization: A Preliminary Analysis and Discussion Document (2011), *available at http://www.copyright.gov/docs/massdigitization/USCOMassDigitizatian_October2011.pdf.*

[3] Notice, 77 FR 64555–61.

[4] U.S. Copyright Office, Report on Orphan Works (2006), *available at http://www.copyright.gov/orphan/arphan-report-full.pdf.*

[5] Shawn Bentley Orphan Works Act of 2008, S. 2913, 110th Cong. (2008); Orphan Works Act of 2008, H.R. 5889, 110th Cong. (2008); Orphan Works Act of 2006, H.R. 5439, 109th Cong. (2006).

[6] *Authors Guild, Inc.* v. *HathiTrust,* 902 F. Supp. 2d 445 (S.D.N.Y. 2012); *Authors Guild, Inc. v. Google Inc.,* 770 F. Supp. 2d 666 (S.D.N.Y. 2011) ("*Google I*").

[7] *See supra* note 5.

[8] *Google I,* 770 F. Supp. 2d at 678. "Google Books" is the larger project that includes the Google Books Library Project and the Google Books Partner Project (formerly "Google Print"). Google commenced its book scanning project (then referred to as "Google Print Library Project") in 2004. In September 2005, the Authors Guild of America and five publisher members of the Association of American Publishers ("AAP") sued Google for copyright infringement. The Google Books Partner Project was created when Google and the publishers announced a settlement agreement in October 2012. References to "Google Books" or the "Google Books case" relate to litigation surrounding the Library Project.

[9] *Authors Guild, Inc.* v. *Google Inc.,* Case No. 05 Civ. 8136 (DC), 2013 WL 6017130, *26 (S.D.N.Y Nov. 14, 2013) ("*Google II*").

ruled that the digitization project undertaken by the HathiTrust Digital Library ("HathiTrust") and its five university partners was largely transformative and protected by fair use.[10] The court, however, did not consider the copyright claims relating to the HathiTrust Orphan Works Project, finding that the issue was not ripe for adjudication because the defendants had suspended the project shortly after the complaint was filed.[11]

In addition to these legal developments, technology has significantly progressed since Congress last considered the orphan works issue. Since 2008, technological developments have arguably mitigated the orphan works problem via vastly improved search tools and database technology. Improved search engine technology allows users to locate rights holders (and vice versa) via image, sound, or video searches. Improved databases, such as the PLUS Registry,[12] and database interoperability allow copyright rights holders to better publicize ownership information. Yet, many argue that these technologies are not being effectively utilized in the context of orphan works and a legislative solution remains necessary.

In light of recent legal and technological developments, the Office is interested in discussing the current need for legislation to address the issues of orphan works and mass digitization. Specifically, the public roundtable meetings will allow participants to discuss whether recent legal developments have obviated the need for legislation, or whether new legislation would resolve or alleviate the concerns identified in the comments. Can the orphan works problem be resolved under existing exceptions and limitations contained in the current Copyright Act, such as fair use? Should this determination hinge on the type of use or user making use of the work? If legislation is deemed necessary, how should it reflect or acknowledge recent developments in fair use law, if at all?

Additionally, the Office would like to discuss the impact of technological advancements. For example, have improved search tools and database technologies mitigated the orphan works problem, or are these technologies not being effectively utilized in the context of orphan works?

Session 2: Defining the Good Faith "Reasonably Diligent Search" Standard

In its 2006 Report, the Copyright Office recommended that Congress amend the Copyright Act to limit the remedies available against good faith users of orphan works after the user performed a generally "reasonably diligent search" to locate the owner of that work. The 2008 bills set forth certain baseline requirements such as searching the Office's online records, and would have required users to consult best practices applicable to the work at issue. Both copyright owners and users would have participated in developing these best practices, which the Register of Copyrights would have coordinated.

The Office is interested in discussing how best to define a good faith, reasonably diligent search in light of changes in the legal and technological environment since 2008, and whether improvements can be made to the standard set forth in the 2008 bills. What are the relative advantages or risks of flexible versus rigidly-defined search standards? Additionally, should the Office participate in developing search criteria or evaluating searches, and should regulations set forth specific search criteria? Moreover, what should be the role of community-developed best practices documents that may guide particular groups of users making particular types of uses, and who should develop these "best practices" documents? Finally, what role should the Office play in developing, monitoring, or certifying search criteria?

Session 3: The Role of Private and Public Registries

One question regarding orphan works is the role public and private registries might play in any orphan works solution. The most obvious of these registries, the Copyright Office's own registration and recordation system, provides a wealth of copyright information but has limitations based on both technological requirements and the fact that registration and recordation is not mandatory in the United States. There are other registries that have ownership information, and there has been some suggestion that the Office should investigate enhancing interoperability between the Office system and private rights registries.[13]

The Office would like to discuss the role registration and recordation may play in helping to more effectively mitigate the orphan works problem. For example, in the context of orphan works, how could the Office facilitate and incentivize owners to register their works and keep their ownership and contact information current? Should failure to register with the Office affect the orphan status of a work? How could any such incentives be reconciled with the United States' obligations under the Berne Convention and other international instruments? Additionally, the Office is interested in learning more about the appropriate role of third party registries (commercial and noncommercial). For example, what could be the Office's role in overseeing or certifying these third party registries? Would it be helpful for the Office to establish a registry requiring users to register their use of, or intent to use, orphan works similar to that envisioned in the Orphan Works Act of 2008?[14] Does the recently-passed UK orphan works legislation, which envisions a key role for a web portal connecting multiple private and public Web sites and databases, present an attractive model for utilizing and organizing these registries in the United States?

Session 4: Types of Works Subject to Orphan Works Legislation, Including Issues Related Specifically to Photographs

As described in the Office's previous Notice and many of the responding comments, orphan works remain a pervasive issue in copyright law. While the issue cuts across all creative sectors, the unique challenges posed by photographs have long been an obstacle to developing an effective orphan works solution. Photographs and other works of visual art may lack or may more easily become divorced from ownership information, especially in the age of social media that has largely transpired since Congress considered the 2008 bills. This lack of identifying

[10] *HathiTrust*, 902 F. Supp. 2d 445.

[11] *Id.* at 455–56.

[12] The PLUS Registry (the "Registry") is an online database created and operated by PLUS Coalition, Inc., an international group of communities "dedicated to creating, using, distributing and preserving images." Users may search the Registry to find rights and descriptive information ("metadata") for any image, and to find current contact information for related creators, rights holders and institutions. Owners may register their images and image licenses to allow authorized users to find rights and descriptive metadata using a specific ID or image recognition. Plus Coalition, Inc., "About," *https://www.plusregistry.org/cgi-bin/WebObjects/PlusDB.woa/1/wo/kl6vPj6TeDu1MqoK7ajbug/0.107.27*. The role of private and public registries is further discussed in Session 3, below.

[13] As mentioned in the Notice, the Office has begun digitizing its historic records and is initiating upgrades to its registration and recordation systems. These projects will facilitate public access to, and thus improve users' ability to investigate, the copyright status of works, including the identification and location of copyright owners. The upgrades to the registration and recordation systems also are meant to facilitate the effective registration of works and recordation of documents related to registered works, helping to ensure that the record and contact information on file with the Office remains accurate. Notice, 77 FR 64558.

[14] H.R. 5889, 110th Cong. sec. 2(a), § 514(b)(3) (2008).

information often prevents users from locating or even initiating a search for orphaned photographs' rights holders. The 2008 bills included a number of provisions specifically aimed at resolving some of the issues specific to photographs.

In light of the peculiar position of photographs, it is important to consider how any orphan works solution might address these specific works, either by creating specific rules or excluding them altogether. Excluding photographs would not be a novel solution; the European Union recently approved an orphan works directive (the "Directive") that provides an exception for noncommercial public interest users making noncommercial public interest uses of orphan works, while providing a general exclusion of photographs from the scheme.[15]

The Office is interested in discussing how to address the problems presented by certain types of works, including specifically photographic and visual arts orphan works. Should an orphan works solution exclude any particular type of work or should it include all copyrighted works? Would the exclusion of certain types of works substantially undermine the effectiveness of any orphan works solution? If all types of works are included, what (if any) special provisions are required to ensure that all copyright owners, such as photographers, are treated equitably within the legislative framework? Do recent developments such as the creation of voluntary registries, like the PLUS Registry,[16] mitigate any of the earlier concerns regarding the treatment of photographs?

Session 5: Types of users and uses subject to orphan works legislation

The Copyright Office's previous orphan works review did not differentiate between commercial and noncommercial uses and users of orphan works. Since then, however, there has been a debate regarding whether an orphan works solution should take into account the user's status as either a commercial or noncommercial entity. For example, the Directive provides an exception for noncommercial public interest users making noncommercial public interest uses of orphan works.[17] Any solution that excludes commercial users and uses, however, may arguably provide an incomplete solution. Some have argued that the policy motivations behind any orphan works legislation logically should extend to commercial uses that may promote the underlying goals of the Copyright Act. The United Kingdom's recently adopted orphan works legislation does not differentiate between commercial and noncommercial users or uses.

The Office thus is interested in learning more about whether an orphan works solution should encompass both commercial and noncommercial uses. Should orphan works legislation apply equally to commercial and noncommercial uses and users? If not, how should specific types of uses and users be treated within the legislative framework? Should orphan works legislation be limited only to uses by noncommercial entities with a public service mission? Should these entities be permitted to use orphan works only for limited purposes such as preservation, or should they be able to broadly use orphan works to provide access to the public? Should commercial entities be able to make commercial use of orphan works? What are the relative advantages or disadvantages of allowing such use?

Day Two

Session 1: Remedies and Procedures Regarding Orphan Works

The Office's 2006 Report did not suggest creation of an exception to copyright for use of orphan works, but instead recommended that Congress limit the remedies that the copyright owner could seek against good faith users of orphan works to injunctive relief and "reasonable compensation" for the use of the work. The Office also recommended a "take-down" option for certain noncommercial users engaged in noncommercial activities, which was incorporated in the proposed 2008 legislation. In addition to the take-down provision, the legislation also would have (1) limited remedies to good faith users of orphan works having performed a reasonably diligent search, (2) been applicable on a case-by-case basis, and (3) permitted rights holders to reasonable compensation, but not statutory damages or attorneys' fees. The Senate bill would have allowed owners to reclaim their works by serving a "Notice of Claim of Infringement," requiring the user to cease the infringement and negotiate in good faith with the rights holder.[18]

The appropriate structure and scope of remedies continues to be a significant issue of concern for both copyright owners and potential users of orphan works. For example, the threat and unpredictable nature of statutory damages, the need for predictability and reasonableness in assessing damages, and the rights available to creators of derivative works based on orphan works are all issues that warrant further discussion.

The Office is interested in discussing remedies and procedures in the context of orphan works. What remedies should be available where orphan works rights holders emerge after a third party has already begun to use an orphaned work? What rights should be available for creators of derivative works based on orphan works? What procedures should be put in place where these situations arise? Does the limitation on liability model still make sense in the current legal environment? Should orphan works legislation instead be re-framed as an exception to copyright as it is in an increasing number of foreign jurisdictions?

Session 2: Mass Digitization, Generally

The Office's 2006 Report and the 2008 proposed legislation did not consider the issue of mass digitization in detail. Although mass digitization was ongoing in 2008, the practice has since become much more prevalent. Thus, it is important to understand how mass digitization fits into an orphan works solution. Because many of the comments submitted in response to the Notice indicated that the issue of mass digitization should be treated separately from the issue of orphan works, it also is important to understand whether mass digitization fits into an orphan works solution.

The Copyright Office would like to discuss the intersection of mass digitization and orphan works at the public roundtable meetings. As a preliminary matter, the Office is interested in discussing what types of digitization projects should be covered by any legislative proposal, including the scope of activities that can be accurately described as "mass digitization." Additionally, it is important to review the relative risks and benefits of mass digitization projects. The Office would like to discuss the types of entities that might

[15] Directive 2012/28/EU, of the European Parliament and of the Council of 25 October 2012 on Certain Permitted Uses of Orphan Works, *available at http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=PE%2036%202012%20REV%202*. Note, however, that photographs embedded in other, covered, works (*e.g.*, photographs contained in books) are included within this scheme. *Id.* at art. 1(4).

[16] *See* Plus Coalition, Inc., supra note 12. Both the 2008 House and Senate bills would have delayed implementation until after such a registry was developed.

[17] *See* Directive, *supra* note 15, at art. 6(2).

[18] S. 2913, 110th Cong. sec. 2(a) § 514(c)(1)(B), 514(b)(1)(A) (2008).

be able to engage in such activities under any legislative proposal, and the types or categories of works that should be covered. Moreover, under what circumstances should mass digitization projects proceed and how may digitized materials be used? How might any mass digitization solution differ from that of a general orphan works solution? Would potential solutions developed in the context of mass digitization ameliorate the issue of orphan works? How might these potential solutions interact?

Session 3: Extended Collective Licensing and Mass Digitization

Several foreign countries have laws that address mass digitization in different ways. For example, recently-passed legislation in the United Kingdom creates a bifurcated approach allowing certain types of individual uses of orphan works and mass digitization.[19] There, individual or occasional users of orphan works may apply for a non-exclusive license from a centralized government or government-sanctioned private agency on payment of a license fee held in escrow should rights holders re-emerge.[20] Users also must perform a diligent search for the rights holder, which must be verified by the authorizing body before a license will be issued.[21] Cultural institutions engaging in mass digitization, on the other hand, may digitize works (including orphan works) in their existing collections through an extended collective licensing regime.[22] The licenses granted are not exclusive and all rights holders have the right to opt out of any license.[23] Hungary has adopted a similar two-tier orphan works solution.[24] Several Nordic countries also have adopted extended collective licensing regimes for limited types of works and uses in the context of mass digitization.[25]

The Office is interesting in reviewing the option of extended collective licensing for purposes of mass digitization in detail. For example, the Office is interested in discussing whether the United States should look abroad to foreign extended collective licensing approaches for ideas on domestic action on the issue of mass digitization. If so, which approach or components of any particular approach present attractive options for a potential U.S. course of action? Should such a system include both commercial and noncommercial uses, or be limited to noncommercial entities? How do extended collective licensing systems work in practice in the countries where they have been adopted? Are there statistics or any longitudinal data regarding the success of extended collective licensing regimes, particularly vis-à-vis orphan works and mass digitization, around the world? Further, would the U.S. political, legal, and market structures, which can be quite different from foreign counterparts, support an extended collective licensing-type solution?

Session 4: The Structure and Mechanics of a Possible Extended Collective Licensing System in the United States

Extended collective licensing systems exist where representatives of copyright owners and users negotiate terms that are binding on both members and similarly situated non-members of the group by operation of law, unless an interested copyright rights holder elects to opt out. Collective management organizations function by establishing, collecting, and distributing these license fees. These organizations typically are sanctioned or overseen by the government. Where these organizations collect licensing fees relating to orphan works, they typically hold these fees until the owner emerges to collect the fee or for a statutorily set period of time. In this way, extended collective licensing may present an option for resolving many of the issues inherent in mass digitization projects, especially as they relate to the incidental digitization of orphan works contained in these digitized collections.

While some other countries have embraced extended collective licensing, the United States currently does not have the legal framework for such a system. Nevertheless, there has been some discussion that extended collective licensing might be helpful in a mass digitization scenario. It is unclear, however, how extended collective licensing could integrate with the current U.S. legal infrastructure to streamline the licensing process, or whether it could possibly upset existing and well-functioning markets for certain copyright-protected works. Moreover, the mechanical operation of such a system is unclear; for example, questions remain regarding procedures whereby copyright rights holders may "opt out" of any extended collective licensing regime.

The Office is interested in discussing specific details of an appropriate extended collective licensing system in the United States for mass digitization purposes. How might an extended collective licensing regime be structured in the United States? Could an extended collective licensing system be compatible with U.S. copyright laws, legal norms, and industry practices? How much direct oversight should the Office or any other governmental entity have over the establishment, authorization, and/or operation of collective management organizations? Are any existing collective management organizations in the United States capable of administering an extended collective licensing regime for mass digitization? If new collective management organizations are created, should they be structured as government entities, nonprofit entities licensed and/or funded by the government, or commercial entities licensed and/or funded privately or by the government?

Additionally, the Office recognizes that the opt-out and orphan works issues inherent in mass digitization projects are ripe for further discussion. For example, should rights holders be permitted to opt out of any extended collective licensing system at any time? How would rights holders' ability to opt out affect licensees who may have made significant investments in the use of licensed works? How should orphan works "incidentally" included in a mass digitization project be handled? Should the collective management organization be responsible for attempting to locate all rights holders and, if so, should a "reasonably diligent search" standard be applied to the organization? How should license fees be calculated and how should remuneration of authors and authors' groups be handled? What

[19] *See* Enterprise and Regulatory Reform Act, 2013, c. 24, § 77, *available at http://www.legislation.gov.uk/ukpga/2013/24/section/77.*

[20] *Id.*

[21] *Id.*

[22] *Id.* In extended collective licensing models, representatives of copyright owners and representatives of users negotiate terms that are binding on all members of the group by operation of law (*e.g.*, all textbook publishers), unless a particular copyright owner opts out. Extended collective licensing regimes authorize the grant of broad licenses to make specified uses of in-copyright works for which it would be unduly expensive to clear rights on a work-by-work basis (*e.g.*, mass digitization of in-copyright works, photocopying in-copyright articles in library settings). The government or a trusted designee typically administers payments. It is not quite compulsory licensing in that the parties (rather than the government) negotiate the rates, but it nevertheless requires a legislative framework and often involves some degree of government oversight. *See* Notice, 77 FR 64559.

[23] Enterprise and Regulatory Reform Act 2013 at Section 77.

[24] 100/2009 (V. 8) Korm. rendelet az árva mü egyes felhasználásainak engedélyezésére vonatkozó részletes szabályokról (Government Regulation on the Detailed Rules Related to the Licensing of Certain Use of Orphan Works), arts. 2(1), 2(2), 3 (Hung.), *available at http://www.hipo.gov.hu/English/jogforras/100_2009.pdf.*

[25] *See, e.g.*, Consolidated Act on Copyright 2010, No. 202, Art. 50–51 (2010) (Denmark); *see also* Copyright Act, No. 404, §§ 13–14 (2010) (Finland).

types of entities should be able to utilize an extended collective licensing system for mass digitization?

Dated: February 5, 2014.

Karyn A. Temple Claggett,

Associate Register of Copyrights and Director of Policy and International Affairs.

[FR Doc. 2014–02830 Filed 2–7–14; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

[NARA–2014–015]

National Industrial Security Program Policy Advisory Committee (NISPPAC)

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulation 41 CFR 101–6, NARA announces an upcoming meeting of the National Industrial Security Program Policy Advisory Committee (NISPPAC).

DATES: The meeting will be held on March 19, 2014, from 10:00 a.m. to 12:00 p.m.

ADDRESSES: National Archives and Records Administration; 700 Pennsylvania Avenue NW., Archivist's Reception Room, Room 105; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: David O. Best, Senior Program Analyst, ISOO, by mail at the above address, telephone (202) 357–5123, or email *david.best@nara.gov*. Contact ISOO at *ISOO@nara.gov* and the NISPPAC at *NISPPAC@nara.gov*.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public. However, due to space limitations and access procedures, the name and telephone number of individuals planning to attend must be submitted to the Information Security Oversight Office (ISOO) no later than Friday, March 14, 2014. ISOO will provide additional instructions for gaining access to the location of the meeting.

Dated: February 5, 2014.

Patrice Little Murray,

Acting Committee Management Officer.

[FR Doc. 2014–02816 Filed 2–7–14; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0239]

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on November 8, 2013 (78 FR 67204).

1. *Type of submission, new, revision, or extension:* Extension.

2. *The title of the information collection:* 10 CFR part 70, "Domestic Licensing of Special Nuclear Material."

3. *Current OMB approval number:* 3150–0009.

4. *The form number if applicable:* Not applicable.

5. *How often the collection is required:* On occasion. Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments may be submitted at any time. Generally, renewal applications are submitted every 10 years and for major fuel cycle facilities updates of the safety demonstration section are submitted every 2 years. Nuclear material control and accounting information is submitted in accordance with specified instructions.

6. *Who will be required or asked to report:* Applicants for and holders of specific NRC licenses to receive title to, own, acquire, deliver, receive, possess, use, or initially transfer special nuclear material.

7. *An estimate of the number of annual responses:* 1,620 responses.

8. *The estimated number of annual respondents:* 606.

9. *An estimate of the total number of hours needed annually to complete the requirement or request:* 89.240.6 hours (81,791.1 hours reporting + 7379.4 hours recordkeeping + 70.1 hours third party disclosure).

10. *Abstract:* Part 70 of Title 10 of the *Code of Federal Regulations* (10 CFR), establishes requirements for licenses to own, acquire, receive, possess, use, and transfer special nuclear material. The information in the applications, reports, and records is used by NRC to make licensing and other regulatory determinations concerning the use of special nuclear material.

The public may examine and have copied for a fee publicly-available documents, including the final supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/*. The document will be available on the NRC's home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by March 12, 2014. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Danielle Y. Jones, Desk Officer, Office of Information and Regulatory Affairs (3150–0009), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be emailed to *Danielle_Y_Jones@omb.eop.gov* or submitted by telephone at 202–395–1741.

The Acting NRC Clearance Officer is Kristen Benney, telephone: 301–415–6355.

Dated at Rockville, Maryland, this 4th day of February, 2014.

For the Nuclear Regulatory Commission.

Kristen Benney,

Acting NRC Clearance Officer, Office of Information Services.

[FR Doc. 2014–02748 Filed 2–7–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2014–0001]

Sunshine Act Meeting Notice

DATE: Weeks of February 10, 17, 24, March 3, 10, 17, 2014.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of February 10, 2014

Wednesday, February 12, 2014

3:00 p.m. Affirmation Session (Public Meeting) (Tentative).

a. Crow Butte Resources, Inc. (Marsland Expansion Area), Appeal by NRC Staff and Crow Butte of LBP–13–6 (May 10, 2013) (Tentative).

b. Tennessee Valley Authority (Sequoyah Nuclear Plant, Units 1 and 2), Tennessee Valley Authority's Appeal of LBP–13–8 (July 30, 2013) and Blue Ridge Environmental Defense League's Petition for Interlocutory Review of LBP–13–8 (July 30, 2013) (Tentative).

Week of February 17, 2014—Tentative

Wednesday, February 19, 2014

9:30 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

1:30 p.m. Briefing on Security Issues (Closed—Ex. 3)

Thursday, February 20, 2014

9:30 a.m. Briefing on Threat Environment Assessment (Closed—Ex. 1)

Week of February 24, 2014—Tentative

There are no meetings scheduled for the week of February 24, 2014.

Week of March 3, 2014—Tentative

Monday, March 3, 2014

1:30 p.m. Briefing on Human Reliability Program Activities and Analyses (Public Meeting) (Contact: Sean Peters, 301–251–7582)

This meeting will be Web cast live at the Web address—*http://www.nrc.gov/.*

Tuesday, March 4, 2014

9:00 a.m. Briefing on Security Issues (Closed—Ex. 1)

1:30 p.m. Briefing on Security Issues (Closed—Ex. 1)

Friday, March 7, 2014

10:00 a.m. Meeting with the Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: Ed Hackett, 301–415–7360)

This meeting will be Web cast live at the Web address—*http://www.nrc.gov/.*

Week of March 10, 2014—Tentative

There are no meetings scheduled for the week of March 10, 2014.

Week of March 17, 2014—Tentative

Friday, March 21, 2014

1:00 p.m. Briefing on Waste Confidence Rulemaking (Public Meeting) (Contact: Andrew Imboden, 301–287–9220)

This meeting will be Web cast live at the Web address—*http://www.nrc.gov/.*

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The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

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The NRC Commission Meeting Schedule can be found on the Internet at:

http://www.nrc.gov/public-involve/public-meetings/schedule.html.

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *Darlene.Wright@nrc.gov.*

Dated: February 5, 2014.

Richard J. Laufer,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2014–02909 Filed 2–6–14; 4:15 pm]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection requests to the Office of Management and Budget (OMB) for Extension without change of a currently approved information collection. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Peace Corps invites the general public to comment on the extension, without change, of currently approved information collection, Peace Corps Report of Physical Examination (OMB 0420–0549). This process is conducted in accordance with 5 CFR 1320.10. Peace Corps received no comments during the 60-day notice.

DATES: Comments regarding this collection must be received on or before March 12, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@ mailto:ddunevant@ peacecorps.govpeacecorps.gov.*

SUPPLEMENTARY INFORMATION:

Method: Applicants gain access to the form via a secure online portal. Applicants have to download the form for their health care provider to complete. The completed form can be scanned and uploaded back into the Applicant's secure Peace Corps online portal or they can be faxed or mailed to the Peace Corps Office of Medical Services.

Title: Peace Corps Report of Physical Examination (PC 1790S).

OMB Control Number: 0420–0549.

Type of Request: Extension without change of a currently approved collection.

Affected Public: Individuals/physicians.

Respondents Obligation to Reply: Voluntary.

Burden to the Public:

a. *Estimated number of respondents/physicians:* 4,000/4,000

b. *Estimated average burden per response:* 90 minutes/45 minutes

c. *Frequency of response:* One time

d. *Annual reporting burden:* 6,000 hours/3,000 hours

e. Estimated annual cost to respondents: Indeterminate

General Description of Collection: The Peace Corps Act requires that Volunteers receive health examinations prior to their service. The information collected is required for consideration for Peace Corps Volunteer service. After completion of the Health History Form and after passing preliminary non-health-related assessments, the Applicant will be "nominated" to a program. This nomination does not

guarantee an invitation to serve, but it does hold a place so the Applicant may proceed with the process. After a review by the Peace Corps pre-service medical staff of the Health History Form and any supplemental forms that the Applicant is required to submit following nomination (covered under OMB control number 0420–0510), the Applicant may be medically pre-cleared. An Applicant who is medically pre-cleared and who accepts an invitation to serve as a Peace Corps Volunteer undergoes a final medical clearance. Final medical clearance is on the basis of a complete physical examination, as documented in a Report of Physical Examination (PC–1790S).

The information contained in the Report of Physical Examination will be used to make an individualized determination as to whether an Applicant for Volunteer service will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems and, if so, to establish the level of medical and other support, if any, that may be required to reasonably accommodate the Applicant.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on February 3, 2014.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2014–02726 Filed 2–7–14; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request, Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection requests to the Office of Management and Budget (OMB) for Extension without change of a currently approved information collection. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Peace Corps invites the general public to comment on the extension, without change, of currently approved information collection, Individual Specific Medical Evaluation Forms (16) (OMB 0420–0550). This process is conducted in accordance with 5 CFR 1320.10. Peace Corps received no comments during the 60-day notice.

DATES: Comments regarding this collection must be received on or before March 12, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@ mailto:ddunevant@ peacecorps.govpeacecorps.gov.*

SUPPLEMENTARY INFORMATION: Volunteers serve in developing countries where western-style healthcare is often not available. Volunteers are placed in remote locations where they may suffer hardship because they have no access to running water and/or electricity. They also may be placed in locations with extreme environmental conditions related to cold, heat or high altitude and they may be exposed to diseases not generally found in the U.S. Volunteers may be placed many hours from the Peace Corps medical office and not have easy access to any health care provider. Therefore, a thorough review of an Applicant's past medical history is an essential first step to determine their suitability for service in Peace Corps.

The forms listed below may be sent to an individual Applicant at one of the following times in the medical review process: (1) After the Applicant completes the Health History Form and receives a nomination; (2) after a Peace Corps nurse reviews the Applicant's Health History Form and any completed forms previously requested; or (3) at the time of the Applicant's physical examination. The information contained in the specific medical evaluation forms will be used to make an individualized determination as to whether an Applicant for Volunteer service will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems.

Method: Applicants gain access to the forms via a secure online portal. Applicants will have to download the forms for their health care providers to complete. Completed forms can be scanned and uploaded back into the Applicant's secure Peace Corps online portal or they can be faxed or mailed to the Peace Corps Office of Medical Services.

Title: Individual Specific Medical Evaluation Forms (16).

OMB Control Number: 0420–0550.

Type of Request: Extension without change of a currently approved collection

Affected Public: Individuals/ Physicians.

Respondents' Obligation To Reply: Voluntary

Burden to the Public:

- Allergy Treatment Form

(a) Estimated number of Applicants/ physicians—100/100

(b) Frequency of response—one time

(c) Estimated average burden per response—20 minutes/10 minutes

(d) Estimated total reporting burden—33.3 hours/16.7 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports that he or she is currently receiving allergy shot treatments, Peace Corps provides the Applicant with an Allergy Treatment Form for his or her treating physician to complete. The Peace Corps is not able to arrange for Volunteers to receive allergy shots during their Peace Corps service. Peace Corps Volunteers generally serve in areas that are isolated and have limited access to Western-trained providers and health care systems. The Applicant completes the form after discussing with his or her physician whether the Applicant will be able to live overseas for 27 months of Peace Corps service without receiving allergy shots. The Applicant is required to certify that the Applicant has discussed stopping allergy shots with his or her physician and that the physician agrees that the allergy shots can be stopped without unreasonable risk of substantial harm to the Applicant's health.

- Asthma Evaluation Form

(a) Estimated number of Applicants/ physicians—500/500

(b) Frequency of response—one time

(c) Estimated average burden per response—75 minutes/30 minutes

(d) Estimated total reporting burden—625 hours/250 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports on the Health History Form symptoms of moderate persistent or severe persistent asthma in the past two years, he or she is provided an Asthma Evaluation Form for the treating physician to complete. The determination of whether the reported symptoms indicate moderate persistent or severe persistent asthma is based on recognized classifications of asthma severity. The Asthma Evaluation Form asks for the physician to document the Applicant's condition of asthma, including any asthma symptoms, triggers, treatments, or limitations or restrictions due to the condition, as well as to certify that the Applicant can safely serve 27 months overseas. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of the Applicant within reasonable proximity to a hospital in case treatment is needed for a severe asthma attack.

• Diabetes Diagnosis Form

(a) Estimated number of Applicants/physicians—36/36

(b) Frequency of response—one time

(c) Estimated average burden per response—75 minutes/30 minutes

(d) Estimated total reporting burden—45 hours/18 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports the condition of diabetes Type 1 on the Health History Form, the Applicant is provided a Diabetes Diagnosis Form for the treating physician to complete. In certain cases, the Applicant may also be asked to have the treating physician complete a Diabetes Diagnosis Form if the Applicant reports the condition of diabetes Type 2 on the Health History Form. The Diabetes Diagnosis Form asks the physician to document the diabetes diagnosis, etiology, possible complications, and treatment, as well as to certify that the Applicant can safely serve 27 months overseas. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of an Applicant who requires the use of insulin in order to ensure that adequate insulin storage facilities are available at the Applicant's site.

• Disease Diagnosis Form

(a) Estimated number of Applicants/physicians—400/400

(b) Frequency of response—one time

(c) Estimated average burden per response—75 minutes/30 minutes

(d) Estimated total reporting burden—500 hours/200 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports on the Health History Form a medical condition of significant severity (other than one covered by another form), he or she may be provided a Disease Diagnosis Form for the treating physician to complete. The Disease Diagnosis Form may also be provided to an Applicant whose responses on the Health History Form indicate that the Applicant may have an unstable medical condition that requires ongoing treatment. The Disease Diagnosis Form asks the physician to document the diagnosis, etiology, possible complications and treatment, as well as to certify that the Applicant can safely serve 27 months overseas. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of an Applicant to take account of the Applicant's medical condition (e.g., avoidance of high altitudes or proximity to a hospital).

• Low Body Mass Index Evaluation Form

(a) Estimated number of Applicants/physicians—50/50

(b) Frequency of response—one time

(c) Estimated average burden per response—105 minutes/60 minutes

(d) Estimated total reporting burden—87.5 hours/50 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports a height and weight on the Health History Form consistent with a body mass index (BMI) that is below 17 for women and 18 for men, the Applicant will be provided a Low Body Mass Index Evaluation Form for a physician to complete. The Low Body Mass Index Evaluation Form asks the physician to indicate whether the Applicant's low BMI is indicative of any condition which could be exacerbated during Peace Corps service. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. Based on the information on the completed form, the Peace Corps may determine that further medical assessments are required.

• Mental Health Treatment Summary Form

(a) Estimated number of Applicants/physicians—150/150

(b) Frequency of response—one time

(c) Estimated average burden per response—105 minutes/60 minutes

(d) Estimated total reporting burden—262.5 hours/150 hours

(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Mental Health Treatment Form is used when an Applicant reports on the Health History Form a history of certain serious mental health conditions, such as bipolar disorder, schizophrenia, mental health hospitalization, attempted suicide or cutting, or treatments or medications related to these conditions. In these cases, an Applicant is provided a Mental Health Treatment Summary Form for a licensed mental health counselor, psychiatrist or psychologist to complete. The Mental Health Treatment Summary Form asks the counselor, psychiatrist or psychologist to document the dates and frequency of therapy sessions, clinical diagnoses, symptoms, course of treatment, psychotropic medications, mental health history, level of functioning, prognosis, risk of exacerbation or recurrence while overseas, recommendations for follow up and any concerns that would prevent the Applicant from completing 27 months of service without undue disruption. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps

Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

• Eating Disorder Treatment Summary Form

(a) Estimated number of Applicants/physicians—232/232
(b) Frequency of response—one time
(c) Estimated average burden per response—105 minutes/60 minutes
(d) Estimated total reporting burden—406 hours/232 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Eating Disorder Treatment Summary Form is used when an Applicant reports a past or current eating disorder diagnosis in the Health History Form. In these cases the Applicant is provided an Eating Disorder Treatment Summary Form for a mental health specialist, preferably with eating disorder training, to complete. The Eating Disorder Treatment Summary Form asks the mental health specialist to document the dates and frequency of therapy sessions, clinical diagnoses, presenting problems and precipitating factors, symptoms, Applicant's weight over the past three years, relevant family history, course of treatment, psychotropic medications, mental health history inclusive of eating disorder behaviors, level of functioning, prognosis, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing 27 months of service without undue disruption due to the diagnosis. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

• Mental Health Current Evaluation Form

(a) Estimated number of Applicants/professional—439/439
(b) Frequency of response—one time
(c) Estimated average burden per response—265 minutes/180 minutes
(d) Estimated total reporting burden—1,939 hours/1,317 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Mental Health Current Evaluation Form is used when an Applicant reports a mental health condition in the Health History Form and it is determined that a current mental health evaluation is needed. A current mental health evaluation might be needed if information on the condition is outdated or previous reports on the condition do not provide enough information to adequately assess the current status of the condition. In these cases, the Applicant will be provided a Mental Health Current Evaluation Form for a licensed mental health counselor, psychiatrist or psychologist to complete over one to three evaluation sessions. The Mental Health Current Evaluation Form asks the mental health professional to document the clinical diagnoses, presenting symptoms, risk of recurrence in a stressful overseas environment, coping strategies, evaluation of overall functioning, psychotropic medications, current psychological tests administered, recommendations for follow up, and any concerns that would prevent the Applicant from completing 27 months of service without undue disruption due to the diagnosis. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

• Alcohol/Substance Abuse Evaluation Form

(a) Estimated number of Applicants/specialist—100/100
(b) Frequency of response—one time
(c) Estimated average burden per response—165 minutes/60 minutes
(d) Estimated total reporting burden—275 hours/100 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Alcohol/Substance Abuse Current Evaluation Form is used when an Applicant reports in the Health History Form a history of substance abuse (i.e., alcohol or drug related problems such as blackouts, daily or heavy drinking patterns or the misuse of illegal or prescription drugs) and that this substance abuse affects the Applicant's daily living or that the Applicant has ongoing symptoms of substance abuse. In these cases, the Applicant is provided an Alcohol/Substance Abuse Current Evaluation Form for a substance abuse specialist to complete. The Alcohol/Substance Abuse Current Evaluation Form asks the substance abuse specialist to document the history of alcohol/substance abuse, dates and frequency of any therapy sessions, which alcohol/substance abuse assessment tools were administered, mental health diagnoses, psychotropic medications, self-harm behavior, current clinical assessment of alcohol/substance use, clinical observations, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing 27 months of service without undue disruption due to the diagnosis. This form is used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to meet the essential eligibility requirements for a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems. This form is also used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate sobriety support or counseling support.

• Mammogram Form

(a) Estimated number of Applicants—224
(b) Frequency of response—one time
(c) Estimated average burden per response—105 minutes
(d) Estimated total reporting burden—392 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Mammogram Form is used with all female Applicants who will be 50 years of age or older, who have received invitations to serve as Volunteers. The purpose of the form is to provide the Peace Corps with results of the Applicant's latest mammogram and to record the wishes of the Applicant regarding routine mammogram screening during service. The Peace Corps uses the information in the Mammogram Form to determine if the Applicant currently has breast cancer and to ascertain whether the Applicant wishes to receive routine mammogram screening while in service. A female Applicant who wishes to receive routine mammogram screening during service will be limited to being placed in a country with mammogram screening capabilities. If the Applicant waives

routine mammogram screening during service, the Applicant's physician also completes this form in order to confirm that the physician has reviewed the Applicant's risk factor assessment and discussed the results with the Applicant and concurs that foregoing screening mammography represents an acceptable risk.

• Pap Screening Form

(a) Estimated number of Applicants/physicians—2,695/2,695
(b) Frequency of response—one time
(c) Estimated average burden per response—25 minutes/15 minutes
(d) Estimated total reporting burden—1,123 hours/674 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Pap Screening Form is used with all female Applicants who have received invitations to serve as Volunteers. They are required to obtain a Pap examination within four months prior to their departure. This form assists the Peace Corps in determining whether a female Applicant with mildly abnormal Pap results will need to be placed in a country with appropriate Pap follow-up capabilities.

• Colon Cancer Screening Form

(a) Estimated number of Applicants—354
(b) Frequency of response—one time
(c) Estimated average burden per response—60 minutes–165 minutes
(d) Estimated total reporting burden—354 hours–973.5 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Colon Cancer Screening Form is used with all Applicants who are 50 years of age or older who have received invitations to serve as Volunteers. The purpose of the form is to provide the Peace Corps with the results of the Applicant's latest colon cancer screening. Any testing deemed appropriate by the American Cancer Society is accepted. The Peace Corps uses the information in the Colon Cancer Screening Form to determine if the Applicant currently has colon cancer. Additional instructions are included pertaining to abnormal test results.

• ECG Form

(a) Estimated number of Applicants/physicians—354/354
(b) Frequency of response—one time
(c) Estimated average burden per response—25 minutes/15 minutes
(d) Estimated total reporting burden—147.5 hours/88.5 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The ECG Form is used with all Applicants who are 50 years of age or older, who have received invitations to serve as Volunteers. The purpose of the form is to provide the Peace Corps with the results of an electrocardiogram. The Peace Corps uses the information in the electrocardiogram to assess whether the Applicant has any cardiac abnormalities that might affect the Applicant's service. Additional instructions are included pertaining to abnormal test results. The electrocardiogram is performed as part of the Applicant's physical examination.

• Reactive Tuberculin Test Evaluation Form

(a) Estimated number of Applicants/physicians—352/352
(b) Frequency of response—one time
(c) Estimated average burden per response—75–105 minutes/30 minutes
(d) Estimated total reporting burden—440–616 hours/176 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Reactive Tuberculin Test Evaluation Form is used when an Applicant, who has received an invitation to serve as Volunteer, reports a history of reactivity to tuberculosis skin testing or a history of BCG vaccination in the Health History Form or if a reactivity is discovered as part of the Applicant's physical examination. In these cases, the Applicant is provided a Reactive Tuberculin Test Evaluation Form for the treating physician to complete. The treating physician is asked to document the type and date of a current TB test, TB test history, diagnostic tests if indicated, treatment history, risk assessment for developing active TB, current TB symptoms, and recommendations for further evaluation and treatment. In the case of a positive result on the TB test, a chest x-ray is also required, along with treatment for latent TB.

• Insulin Dependent Supplemental Documentation Form

(a) Estimated number of Applicants/physicians—8/8
(b) Frequency of response—one time
(c) Estimated average burden per response—70 minutes/60 minutes
(d) Estimated total reporting burden—9.3 hours/8 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Insulin Dependent Supplemental Documentation Form is used with Applicants, who have received invitations to serve as Volunteers, and who have reported on the Health History Form that they have insulin dependent diabetes. In these cases, the Applicant is provided an Insulin Dependent Supplemental Documentation Form for the treating physician to complete. The Insulin Dependent Supplemental Documentation Form asks the treating physician to document that he or she has discussed with the Applicant medication (insulin) management, including whether an insulin pump is required, as well as the care and maintenance of all required diabetes related monitors and equipment. This form assists the Peace Corps in determining whether the Applicant will be in need of insulin storage while in service and, if so, will assist the Peace Corps in determining an appropriate placement for the Applicant.

• Prescription for Eyeglasses Form

(a) Estimated number of Applicants/physicians—2,432/2,432
(b) Frequency of response—one time
(c) Estimated average burden per response—105 minutes/15 minutes
(d) Estimated total reporting burden—4,256 hours/608 hours
(e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Prescription for Eyeglasses Form is used with Applicants, who have received invitations to serve as Volunteers, and who have reported on the Health History Form that they use corrective lenses or otherwise have uncorrected vision that is worse than 20/40. In these cases, Applicants are provided a Prescription for Eyeglasses Form for their prescriber to indicate eyeglasses frame measurements, lens instructions, type of lens, gross vision and any special instructions. This form is used in order to enable the Peace Corps to obtain replacement eyeglasses for a Volunteer during service.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on February 3, 2014.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2014–02719 Filed 2–7–14; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection requests to the Office of Management and Budget (OMB) for Extension without change of a currently approved information collection. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Peace Corps invites the general public to comment on the extension, without change, of currently approved information collection, Peace Corps Volunter Health History Form (OMB 0420–0510). This process is conducted in accordance with 5 CFR 1320.10. Peace Corps received no comments during the 60-day notice.

DATES: Comments regarding this collection must be received on or before March 12, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@ mailto:ddunevant@ peacecorps.govpeacecorps.gov.*

SUPPLEMENTARY INFORMATION:

Method: The Health History Form will be completed online in an interactive process in which only questions relevant to each Applicant's medical history (based on responses to previous questions) are presented.

Title: Peace Corps Volunter Health History form (PC 1789).

OMB Control Number: 0420–0510.

Type of Request: Extension without change of a currently approved collection.

Affected Public: Individuals or households

Respondents Obligation To Reply: Voluntary

Burden to the Public:

a. Estimated number of respondents.	10,000
b. Estimated average burden per response.	45 minutes
c. Frequency of response	one time
d. Annual reporting burden ..	7,500 hours
e. Estimated annual cost to respondents.	Indeterminate

General Description of Collection: The Peace Corps Act requires that Volunteers receive health examinations prior to their service. The information collected is required for consideration for Peace Corps Volunteer service. The Health History Form is used to document the medical history of each individual Applicant. It is a self-report of pre-existing medical conditions and is used to help determine whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without undue disruption due to health problems.

Request For Comment: Peace Corps invites comments on whether the proposed collection of information is necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice issued in Washington, DC on February 3, 2014.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2014–02723 Filed 2–7–14; 8:45 am]

BILLING CODE 6051–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is forwarding 3 Information Collection Requests (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collections of information to determine (1) the practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

1. Title and purpose of information collection: Certification Regarding Rights to Unemployment Benefits; OMB 3220–0079.

Under Section 4 of the Railroad Unemployment Insurance Act (RUIA), an employee who leaves work voluntarily is disqualified for unemployment benefits unless the employee left work for good cause and is not qualified for unemployment benefits under any other law. RRB Form UI–45, Claimant's Statement—Voluntary Leaving of Work, is used by the RRB to obtain the claimant's statement when the claimant, the claimant's employer, or another source indicates that the claimant has voluntarily left work.

Completion of Form UI–45 is required to obtain or retain benefits. One response is received from each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (78 FR 70358 on November 25, 2013) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Certification Regarding Rights to Unemployment Benefits.

OMB Control Number: 3220–0079.

Form(s) submitted: UI–45.

Type of request: Extension without change of a currently approved collection.

Affected public: Individuals or Households.

Abstract: In administering the disqualification for the voluntary leaving of work provision of Section 4 of the Railroad Unemployment Insurance Act, the Railroad Retirement Board investigates an unemployment claim that indicates the claimant left voluntarily. The certification obtains

information needed to determine if the leaving was for good cause.

Changes proposed: The RRB proposes no changes to Form UI–45.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
UI–45	200	15	50

2. Title and purpose of information collection: Railroad Separation Allowance or Severance Pay Report; OMB 3220–0173.

Section 6 of the Railroad Retirement Act provides for a lump-sum payment to an employee or the employee's survivors equal to the Tier II taxes paid by the employee on a separation allowance or severance payment for which the employee did not receive credits toward retirement. The lump-sum is not payable until retirement benefits begin to accrue or the employee dies. Also, Section 4 (a-1)(iii) of the Railroad Unemployment Insurance Act provides that a railroad employee who is paid a separation allowance is disqualified for unemployment and sickness benefits for the period of time the employee would have to work to earn the amount of the allowance. The reporting requirements are specified in 20 CFR 209.14.

In order to calculate and provide payments, the Railroad Retirement Board (RRB) must collect and maintain records of separation allowances and severance payments which were subject to Tier II taxation from railroad employers. The RRB uses Form BA–9, Report of Separation Allowance or Severance Pay, to obtain information from railroad employers concerning the separation allowances and severance payments made to railroad employees and/or the survivors of railroad employees. Employers currently have the option of submitting their reports on paper Form BA–9 (or in like format) on a CD–ROM disk, or by File Transfer Protocol (FTP), or secure Email. Completion is mandatory. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (78 FR 70358 on November 25, 2013) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Railroad Separation Allowance or Severance Pay Report.

OMB Control Number: 3220–0173.

Form(s) submitted: BA–9.

Type of request: Extension without change of a currently approved collection.

Affected public: Private Sector; Businesses or other for profits.

Abstract: Section 6 of the Railroad Retirement Act provides for a lump-sum payment to an employee or the employee's survivor equal to the Tier II taxes paid by the employee on a separation allowance or severance payment for which the employee did not receive credits toward retirement. The collection obtains information concerning the separation allowances and severance payments paid from railroad employers.

Changes proposed: The RRB proposes no changes to Form BA–9.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
BA–9 (paper)	265	76	336
BA–9 (CD–ROM)	60	76	76
BA–9 (secure Email)	25	76	32
BA–9 (FTP)	10	76	13
Total	360	.....	457

3. Title and purpose of information collection: Earnings Information Request; OMB 3220–0184. Under Section 2 of the Railroad Retirement Act, an annuity is not payable, or is reduced for any month(s) in which the beneficiary works for a railroad or earns more than prescribed amounts.

The provisions relating to the reduction or non-payment of annuities by reason of work are prescribed in 20 CFR 230.

The RRB utilizes Form G–19–F, Earnings Information Request, to obtain earnings information that either had not been previously reported or erroneously reported by a beneficiary. The claimant is asked to enter the date they stopped working, if applicable.

If a respondent fails to complete the form, the RRB may be unable to pay them benefits. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (78 FR 70359 on November 25, 2013) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Earnings Information Request.

OMB Control Number: 3220–0184.

Form(s) submitted: G–19–F.

Type of request: Extension without change of a currently approved collection.

Affected public: Individuals or Households.

Abstract: Under Section 2 of the Railroad Retirement Act, an annuity is not payable, or is reduced for any month(s) in which the beneficiary works for a railroad or earns more than prescribed amounts. The collection obtains earnings information not previously or erroneously reported by a beneficiary.

Changes proposed: The RRB proposes to revise the G–19–F to allow the claimant who has not stopped working to indicate if they will stop working within 90 days.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–19–F	900	8	120

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.*

Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, 60611–2092 or *Charles.Mierzwa@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2014–02805 Filed 2–7–14; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30905; File No. 812–14124]

KKR Series Trust and Prisma Capital Partners LP; Notice of Application

AGENCY: Securities and Exchange Commission.

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 15(a) of the Act and rule 18f-2 under the Act, as well as from certain disclosure requirements.

Summary of Application: Applicants request an order that would permit them to enter into and materially amend sub-advisory agreements with Wholly-Owned Sub-Advisers (as defined below) and non-affiliated sub-advisers without shareholder approval and would grant relief from certain disclosure requirements.

Applicants: KKR Series Trust (the "Trust"), and Prisma Capital Partners LP ("Prisma").

Filing Dates: The application was filed on February 15, 2013, and amended on June 25, 2013, and November 6, 2013.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on March 3, 2014, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. The Trust, c/o Nicole J. Macarchuk, Esq., KKR Asset Management LLC, 555 California Street, 50th Floor, San Francisco, California 94104; and Prisma, c/o Francis J. Conroy and Vince Cuticello, Esq., Prisma Capital Partners LP, One Penn Plaza, Suite 3515, New York, New York 10119.

FOR FURTHER INFORMATION CONTACT: Steven I. Amchan, Senior Counsel, at (202) 551–6826, or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is organized as a Delaware statutory trust and is registered with the Commission as an open-end management investment company under the Act. The Trust may offer one or more series of shares (each a "Series" and collectively, "Series") with its own distinct investment objectives, policies and restrictions. Prisma is the investment adviser to KKR Alternative Strategies Fund, a series of the Trust (the "Multi-Manager Fund"). Prisma is a Delaware limited partnership and is a subsidiary of KKR & Co. L.P.[1]

2. Applicants request an order to permit the Adviser, subject to the approval of the board of trustees of the Trust (the "Board"), including a majority of the trustees who are not "interested persons," as defined in section 2(a)(19) of the Act, of the Series or the Adviser ("Independent Trustees"), to, without obtaining shareholder approval: (i) Select Sub-Advisers to manage all or a portion of the assets of a Sub-Advised Series and enter into Sub-Advisory Agreements (as defined below) with the Sub-Advisers, and (ii) materially amend Sub-Advisory Agreements with the Sub-Advisers.[2] Applicants request that the relief apply to the Applicants, as well as to any future Series and any other existing or future registered open-end management investment company or series thereof that is advised by an Adviser, uses the multi-manager structure described in the application ("Multi-Manager Structure"), and complies with the terms and conditions of the application ("Sub-Advised Series").[3]

3. Prisma will serve as the investment adviser to the Multi-Manager Fund pursuant to an investment advisory agreement with the Trust (the "Investment Management Agreement"). The Investment Management Agreement was approved by the Board, including a majority of the Independent Trustees, and prior to the commencement date, will be approved by the initial shareholder of the Multi-Manager Fund as required by sections 15(a) and 15(c) of the Act and rule 18f-2 thereunder. The terms of the Investment

[1] The Trust and Prisma, together, the "Applicants." Prisma or another investment adviser controlling, controlled by or under common control with Prisma or its successors, each, an "Adviser." For purposes of the requested order, "successor" is limited to an entity that results from reorganization into another jurisdiction or a change in the type of business organization. Prisma is, and any other Adviser will be, registered with the Commission as an investment adviser under the Investment Advisers Act of 1940, as amended ("Advisers Act").

[2] Shareholder approval will continue to be required for any other sub-adviser change (not otherwise permitted by rule and material amendments to an existing sub-advisory agreement with any sub-adviser other than a Non-Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser (all such changes referred to as "Ineligible Affiliated Sub-Adviser Changes").

[3] The Trust is the only registered open-end investment company that currently intend to rely on the requested order. The Multi-Manager Fund is the only Series that currently intends to be a Sub-Advised Series. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application. The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, who is an affiliated person, as defined in Section 2(a)(3) of the Act, of the Trust, a Sub-Advised Series, or an Adviser, other than by reason of serving as a sub-adviser to one or more of the Sub-Advised Series ("Affiliated Sub-Adviser").

Management Agreements comply with section 15(a) of the Act. Each other Investment Management Agreement will comply with section 15(a) of the Act and will be similarly approved.

4. Under the terms of the Investment Management Agreement, Prisma, subject to the supervision of the Board, will provide continuous oversight of the investment management of the assets of the Multi-Manager Fund. For its services to the Multi-Manager Fund under the Investment Management Agreement, Prisma will receive an investment management fee from the Multi-Manager Fund based on the average daily net assets of the Multi-Manager Fund. Consistent with the contemplated Multi-Manager Structure, Prisma may, subject to the approval of the Board, including a majority of the Independent Trustees, delegate portfolio management responsibilities of all or a portion of the assets of the Multi-Manager Fund to one or more Sub-Advisers.[4]

5. Pursuant to the Investment Management Agreement, Prisma has overall responsibility for the management of the Multi-Manager Fund; these responsibilities include recommending the removal or replacement of Sub-Advisers, determining the portion of the Multi-Manager Fund's assets to be managed by any given Sub-Adviser and reallocating those assets as necessary from time to time.

6. Pursuant to the authority under the Investment Management Agreement, Prisma will be permitted to enter into investment sub-advisory agreements with Sub-Advisers ("Sub-Advisory Agreements") on behalf of the Multi-Manager Fund.[5] The terms of each Sub-Advisory Agreement will comply fully with the requirements of section 15(a) of the Act. The Sub-Advisory Agreements will be approved by the Board, including a majority of the Independent Trustees, in accordance with sections 15(a) and 15(c) of the Act. The Sub-Advisers, subject to the supervision of Prisma and oversight of the Board, will determine the securities and other instruments to be purchased, sold or entered into by the Multi-Manager Fund's portfolio or a portion thereof, and will place orders with brokers or dealers that they select. Prisma will compensate each Sub-Adviser out of the fee paid to Prisma under the Investment Management Agreement.

7. Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser pursuant to the following procedures ("Modified Notice and Access Procedures"): (a) within 90 days after a new Sub-Adviser is hired for any Sub-Advised Series, that Sub-Advised Series will send its shareholders either a Multi-Manager Notice or a Multi-Manager Notice and Multi-Manager Information Statement;[6] and (b) the Sub-Advised Series will make the Multi-Manager Information Statement available on the Web site identified in the Multi-Manager Notice no later than when the Multi-Manager Notice (or Multi-Manager Notice and Multi-Manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days. Applicants state that, in the circumstances described in the application, a proxy solicitation to approve the appointment of new Sub-Advisers provides no more meaningful information to shareholders than the proposed Multi-Manager Information Statement. Applicants state that the Board would comply with the requirements of sections 15(a) and 15(c) of the Act before entering into or amending Sub-Advisory Agreements.

8. Applicants also request an order exempting the Sub-Advised Series from certain disclosure obligations that may require the Applicants to disclose fees paid by the Adviser to each Sub-Adviser. Applicants seek relief to permit each Sub-Advised Series to disclose (as a dollar amount and a percentage of the Sub-Advised Series' net assets): (a) the aggregate fees paid to the Adviser and any Wholly-Owned Sub-Advisers; and (b) the aggregate fees paid to Non-Affiliated Sub-Advisers (the "Aggregate Fee Disclosure"). If a sub-adviser, other than a Non-Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser, is employed to provide management services to a Sub-Advised Series, that Sub-Advised Series will provide separate disclosure of any fees paid to such sub-adviser.

Applicants' Legal Analysis

1. Section 15(a) of the Act states, in part, that it is unlawful for any person to act as an investment adviser to a registered investment company "except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company." Rule 18f–2 under the Act states that any "matter required to be submitted . . . to the holders of the outstanding voting securities of a series company shall not be deemed to have been effectively acted upon unless approved by the holders of a majority of the outstanding voting securities of each class or series of stock affected by such matter." Further, rule 18(f)–2(c)(1) under the Act provides that a vote to approve an investment advisory contract required by section 15(a) of the Act "shall be deemed to be effectively acted upon with respect to any class or series of securities of such registered investment company if a majority of the outstanding voting securities of such class or series vote for the approval of such matter."

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the "advisory fee payable" by the investment company, including the total dollar amounts that the investment company "paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years."

3. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the Exchange Act. Items 22(c)(1)(ii),

[4] As used herein, a "Sub-Adviser" for a Series may be: (1) An indirect or direct "wholly-owned subsidiary" (as such term is defined in the Act) of the Adviser for that Series, or (2) a sister company of the Adviser for that Series that is an indirect or direct "wholly-owned subsidiary" (as such term is defined in the Act) of the same company that, indirectly or directly, wholly owns the Adviser (each of (1) and (2) a "Wholly-Owned Sub-Adviser" and collectively, the "Wholly-Owned Sub-Advisers"), or (3) not an "affiliated person" (as such term is defined in section 2(a)(3) of the Act) of the Series, the Trust, or an Adviser, except to the extent that an affiliation arises solely because the sub-adviser serves as a Sub-Adviser to a Series (each a "Non-Affiliated Sub-Adviser").

[5] If the name of any Series contains the name of a Sub-Adviser, that name will be preceded by the name of the Adviser.

[6] A "Multi-Manager Notice" will be modeled on a Notice of Internet Availability as defined in rule 14a-16 under the Securities Exchange Act of 1934 ("Exchange Act"), and specifically will, among other things: (a) summarize the relevant information regarding the new Sub-Adviser; (b) inform shareholders that the Multi-Manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-Manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-Manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-Manager Information Statement may be obtained, without charge, by contacting the Sub-Advised Series. A "Multi-Manager Information Statement" will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Exchange Act for an information statement, except as modified by the order to permit Aggregate Fee Disclosure, as defined below. Multi-Manager Information Statements will be filed with the Commission via the EDGAR system.

22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the "rate of compensation of the investment adviser," the "aggregate amount of the investment adviser's fee," a description of the "terms of the contract to be acted upon," and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission by order upon application may conditionally or unconditionally exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that their requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to review and approval of the Board, to select Sub-Advisers who the Adviser believes can achieve the Sub-Advised Series' investment objectives. Applicants assert that, from the perspective of the shareholder, the role of the Sub-Advisers is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of the Sub-Advised Series are paying the Adviser—the selection, supervision and evaluation of the Sub-Advisers, including Wholly-Owned Sub-Advisers—without incurring unnecessary delays or expenses is appropriate in the interest of the Sub-Advised Series' shareholders and will allow such Sub-Advised Series to operate more efficiently. Applicants state that each Investment Management Agreement will continue to be fully subject to section 15(a) of the Act and rule 18f-2 under the Act, and was approved by the Board, including a majority of the Independent Trustees, in the manner required by sections 15(a) and 15(c) of the Act. Applicants are not seeking an exemption with respect to the Investment Management Agreements.

7. Applicants assert that disclosure of the individual fees that the Adviser would pay to the Sub-Advisers would not serve any meaningful purpose. Applicants contend that the primary reasons for requiring disclosure of individual fees paid to Sub-Advisers are to inform shareholders of expenses to be charged by a particular Sub-Advised Series and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the advisory fee paid to the Adviser will be fully disclosed and, therefore, shareholders will know what the Sub-Advised Series' fees and expenses are and will be able to compare the advisory fees a Sub-Advised Series is charged to those of other investment companies. Applicants assert that the requested relief would benefit shareholders of the Sub-Advised Series because it would improve the Adviser's ability to negotiate the fees paid to Sub-Advisers. Applicants assert that the Adviser's ability to negotiate with the various Sub-Advisers would be adversely affected by public disclosure of fees paid to each Sub-Adviser. Applicants state that if the Adviser is not required to disclose the Sub-Advisers' fees to the public, the Adviser may be able to negotiate rates that are below a Sub-Adviser's "posted" amounts. Applicants submit that the relief will also encourage Sub-Advisers to negotiate lower sub-advisory fees with the Adviser if the lower fees are not required to be made public.

8. For the reasons discussed above, Applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act. Applicants state that the operation of the Sub-Advised Series in the manner described in the application must be approved by shareholders of a Sub-Advised Series before that Sub-Advised Series may rely on the requested relief. In addition, Applicants state that the proposed conditions to the requested relief are designed to ensure that shareholder interests are adequately protected through Board oversight. Applicants assert that conditions 6, 7, 10 and 11 are designed to provide the Board with sufficient independence and the resources and information it needs to monitor and address any conflicts of interest. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:[7]

1. Before a Sub-Advised Series may rely on the order requested in the application, the operation of the Sub-Advised Series pursuant to the Multi-Manager Structure, including the hiring of Wholly-Owned Sub-Advisers, will be approved by a majority of the Sub-Advised Series' outstanding voting securities, as defined in the Act, which in the case of a Sub-Advised Series whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, will be by the sole initial shareholder before offering the Sub-Advised Series' shares to the public.

2. The prospectus for each Sub-Advised Series will disclose the existence, substance, and effect of any order granted pursuant to the application. Each Sub-Advised Series will hold itself out to the public as employing the Multi-Manager Structure described in the application. A Sub-Advised Series' prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the Board, to oversee the Sub-Advisers and recommend their hiring, termination and replacement.

3. The Adviser will provide general management services to a Sub-Advised Series, including overall supervisory responsibility for the general management and investment of the Sub-Advised Series' assets. Subject to review and approval of the Board, the Adviser will (a) set a Sub-Advised Series' overall investment strategies, (b) evaluate, select, and recommend Sub-Advisers to manage all or a portion of a Sub-Advised Series' assets, and (c) implement procedures reasonably designed to ensure that Sub-Advisers comply with a Sub-Advised Series' investment objective, policies and restrictions. Subject to review by the Board, the Adviser will (a) when appropriate, allocate and reallocate a Sub-Advised Series' assets among multiple Sub-Advisers; and (b) monitor and evaluate the performance of Sub-Advisers.

[7] Applicants will only comply with conditions 8 and 12 if they rely on the relief that would allow them to provide Aggregate Fee Disclosure.

4. A Sub-Advised Series will not make any Ineligible Affiliated Sub-Adviser Changes without the approval of the shareholders of the applicable Sub-Advised Series.

5. A Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser within 90 days after the hiring of the new Sub-Adviser pursuant to the Modified Notice and Access Procedures.

6. At all times, at least a majority of the Board will be Independent Trustees, and the selection and nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

7. Independent Legal Counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

8. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Sub-Advised Series basis. The information will reflect the impact on profitability of the hiring or termination of any sub-adviser during the applicable quarter.

9. Whenever a sub-adviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

10. Whenever a sub-adviser change is proposed for a Sub-Advised Series with an Affiliated Sub-Adviser or Wholly-Owned Sub-Adviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that such change is in the best interests of the Sub-Advised Series and its shareholders, and does not involve a conflict of interest from which the Adviser or the Affiliated Sub-Adviser or Wholly-Owned Sub-Adviser derives an inappropriate advantage.

11. No Board member or officer of a Sub-Advised Series or any partner, director, manager, or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person), any interest in a Sub-Adviser, except for (i) ownership of interests in the Adviser or any entity, other than a Wholly-Owned Sub-Adviser, that controls, is controlled by, or is under common control with the Adviser; or (ii) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly traded company that is either a Sub-Adviser or an entity that controls, is controlled by, or is under common control with a Sub-Adviser.

12. Each Sub-Advised Series will disclose the Aggregate Fee Disclosure in its registration statement.

13. In the event the Commission adopts a rule under the Act providing substantially similar relief to that requested in the application, the requested order will expire on the effective date of that rule.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–02766 Filed 2–7–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Wednesday, February 12, 2014 at 2:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Consideration of amicus participation; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: February 5, 2014.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2014–02880 Filed 2–6–14; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71469; File No. SR–FICC–2014–801]

Self-Regulatory Organizations; The Fixed Income Clearing Corporation; Notice of Filing of an Advance Notice Concerning the Government Security Division's Inclusion of GCF Repo® Positions in Its Intraday Participant Clearing Fund Requirement Calculation, and Its Hourly Internal Surveillance Cycles

February 4, 2014.

Pursuant to Section 806(e)(1)(A) of the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act")[1] and Rule 19b–4(n)(1)(i) of the Securities Exchange Act of 1934 ("Act"),[2] notice is hereby given that on January 10, 2014, The Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") the advance notice as described in Items I, II and III below, which Items have been prepared by FICC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Advance Notice

This advance notice is filed by the Government Securities Division (the "GSD") of FICC in connection with including GCF Repo®[3] positions in its intraday (i.e., noon) participant Clearing Fund requirement calculation, and its hourly internal surveillance cycles. The model change is described in additional detail below.

[1] 12 U.S.C. 5465(e)(1)(A). The Financial Stability Oversight Council designated FICC a systemically important financial market utility on July 18, 2012. *See* Financial Stability Oversight Council 2012 Annual Report, Appendix A, *http://www.treasury.gov/initiatives/fsoc/Documents/2012%20Annual%20Report.pdf.* Therefore, FICC is required to comply with Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] The GCF Repo® service enables dealers to trade general collateral repos, based on rate, term, and underlying product, throughout the day without requiring intra-day, trade-for-trade settlement on a Deliver-versus-Payment (DVP) basis. The service fosters a highly liquid market for securities financing.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, FICC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. FICC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

(a) GSD plans to incorporate GCF Repo positions in its intraday (i.e., noon) participant Clearing Fund requirement calculation, and its hourly internal surveillance cycles. This enhancement is intended to align GSD's risk management calculations and monitoring with the changes that have been implemented to the tri-party infrastructure by the Tri-Party Reform Task Force (the "Task Force") [4] specifically, with respect to locking up of GCF Repo collateral until 3:30 p.m. (EST) rather than 7:45 a.m. (EST).

(b) The proposed change is consistent with Rule 17Ad–22 [5] (the "Clearing Agency Standards") which establishes the minimum requirements regarding how registered clearing agencies must maintain effective risk management procedures and controls. Specifically, consistent with Rule 17Ad-22(b)(1) [6] and (b)(2),[7] FICC's more accurate and timely calculations around and monitoring of GCF Repo activity will better enable FICC to respond in the event that a member defaults. As such, FICC believes that the proposal promotes robust risk management and the safety and soundness of FICC's operations, which reduce systemic risk and support the stability of the broader financial system which is consistent with the Clearing Agency Standards.[8]

[4] The Tri-Party Repo Infrastructure Task Force was formed in September 2009 under the auspices of the Payments Risk Committee, a private-sector body sponsored by the Federal Reserve Bank of New York. The Task Force's goal is to enhance the repo market's ability to navigate stressed market conditions by implementing changes that help better safeguard the market. DTCC has worked in close collaboration with the Task Force on their reform initiatives.

[5] 17 CFR 240.17Ad–22.

[6] 17 CFR 240.17Ad–22(b)(1).

[7] 17 CFR 240.17Ad–22(b)(2).

[8] 17 CFR 240.17Ad–22.

(B) Self-Regulatory Organization's Statements on Comments on the Advance Notice Received From Members, Participants, or Others

Written comments relating to the change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

(C) Advance Notice Filed Pursuant to Section 806(e) of the Payment, Clearing and Settlement Supervision Act

Description of Change

(i) Overview

GSD plans to incorporate GCF Repo positions in its intraday (i.e., noon) participant Clearing Fund requirement calculation, and its hourly internal surveillance cycles. This enhancement is intended to align GSD's risk management calculations and monitoring with the changes that have been implemented to the tri-party infrastructure by the Task Force.

Historically, the GCF Repo collateral had been unwound by approximately 7:45 a.m. (all times are New York time). In connection with the Task Force's tri-party reform, GCF Repo collateral now remains locked up until 3:30 p.m., with substitutions permitted intraday at the times established by each clearing bank. Because the GCF Repo collateral was unwound at 7:45 a.m., the current production system does not include GCF Repo collateral in the GSD intraday Clearing Fund requirement calculation, and its hourly surveillance cycles. To account for the risk associated with the GCF Repo positions, GSD's margin requirements currently apply a "higher of" standard, which means that the margin calculation takes the higher of the prior night's core charge [9] (which includes GCF Repo collateral) or the current day's noon core charge (which does not [10] include GCF Repo collateral). However, now that the collateral is locked-up until 3:30 p.m., the intraday Clearing Fund requirements and hourly surveillance calculations will be based on the actual locked-up GCF Repo collateral. In the ordinary course of business, the "higher of" standard will not apply. However, this standard will remain available in the event that one or both clearing banks do not provide intraday GCF Repo position data because such clearing bank, as applicable, is unable to provide the data.

In connection with this initiative, FICC will have an extended member parallel period of at least 6 weeks during which GCF Repo participants will be able to view their production and test requirements on a daily basis. This will allow members to assess the impact of the change in margining for the mid-day cycle and potentially adjust their GCF Repo activity prior to implementation of the change.

Anticipated Effect on and Management of Risks

FICC believes that the proposed changes will improve its risk management by providing a more accurate and timely view of member positions and their corresponding exposures.

This enhancement is intended to align GSD's risk management calculations and monitoring with the changes that have been implemented to the tri-party infrastructure by the Task Force.

Prior to implementation of the proposed changes, several steps were and/or will be taken to prepare for the changes and to prepare members for the changes. These steps include internal review of the data available in the test environment, customer outreach and the parallel period for members.

FICC believes it is important to incorporate the proposed changes in its risk management process as soon as possible because such changes will allow GSD to use more accurate position information in its margin calculations. Because FICC's risk engine has not yet incorporated the locked-up GCF Repo positions in intraday risk calculations, FICC cannot at this time provide a specific estimate of the impact of this enhancement.

FICC believes that the proposed changes will better reflect the actual risk in its members' portfolios. For members who participate in the GCF Repo service, this change will impact their Clearing Fund requirements. However, because of the parallel period, members will have time to review the possible impact and potentially modify their settlement and trading activity to align with the changes to the intraday margin calculation. FICC's parallel period will cover at least six weeks to give customers ample time to review the impact and consider changes to their portfolios.

[9] The core charge consists primarily of Value-at-Risk, the Implied Volatility Charge (also known as the Augmented Volatility Multiplier) and the Coverage Component.

[10] Since GCF collateral is excluded, only DVP positions are included in the noon core charge.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The designated clearing agency may implement this change if it has not

received an objection to the proposed change within 60 days of the later of (i) the date that the Commission receives notice of the proposed change, or (ii) the date the Commission receives any further information it requests for consideration of the notice. The designated clearing agency shall not implement this change if the Commission has any objection.

The Commission may, during the 60-day review period, extend the review period for an additional 60 days for proposed changes that raise novel or complex issues, subject to the Commission providing the designated clearing agency with prompt written notice of the extension. The designated clearing agency may implement a change in less than 60 days from the date of receipt of the notice of proposed change by the Commission, or the date the Commission receives any further information it requested, if the Commission notifies the designated clearing agency in writing that it does not object to the proposed change and authorizes the designated clearing agency to implement the change on an earlier date, subject to any conditions imposed by the Commission.

The designated clearing agency shall post notice on its Web site of proposed changes that are implemented.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FICC–2014–801 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2014–801. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method of submission. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.dtcc.com/~/media/Files/Downloads/legal/rule-filings/2014/ficc/SR-FICC-2014-801-advance-notice.ashx*. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2014–801 and should be submitted on or before March 3, 2014.

By the Commission.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–02744 Filed 2–7–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71475; File No. SR–NYSEArca–2014–09]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services To Eliminate the Tape B Adding Tier and Modify the Tape B Step Up Tier

February 4, 2014.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on January 23, 2014, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services ("Fee Schedule") to eliminate the Tape B Adding Tier and modify the Tape B Step Up Tier. The Exchange proposes to implement the changes on February 1, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to eliminate the Tape B Adding Tier and modify the Tape B Step Up Tier. The Exchange proposes to implement the changes on February 1, 2014.

Currently, under the Tape B Adding Tier, the Exchange provides a $0.0002 per share credit for ETP holders, including Market Makers, that provide liquidity of 0.675% or more of U.S. consolidated ADV ("CADV") in Tape B Securities ("U.S. Tape B CADV") for the billing month. When the Exchange proposed the Tape B Adding Tier credit, the Exchange expected it to incentivize ETP Holders to provide additional liquidity to the Exchange in Tape B Securities;[4] however, the credit has not had the intended effect. Accordingly, the Exchange proposes to eliminate the Tape B Adding Tier.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 69926 (July 3, 2013), 78 FR 41154 (July 9, 2013) (SR–NYSEArca–2013–67).

The Exchange also proposes to revise the Tape B Step Up Tier. Currently, ETP Holders, including Market Makers, that, on a daily basis, measured monthly, directly execute providing volume in Tape B Securities during the billing month ("Tape B Adding ADV") that is equal to at least the ETP Holder's May 2013 Tape B Adding ADV plus 0.275% of U.S. Tape B CADV for the billing month receive a credit of $0.0004 per share for orders that provide liquidity to the Exchange in Tape B Securities, which is in addition to the ETP Holder's Tiered or Basic Rate credit(s). The Exchange proposes to revise the threshold for qualifying for the tier by requiring ETP Holders, including Market Makers, on a daily basis, measured monthly, to directly execute Tape B Adding ADV that is equal to at least 0.275% of the U.S. Tape B CADV for the billing month over the ETP Holder's or Market Maker's May 2013 Tape B Adding ADV taken as a percentage of Tape B CADV ("Tape B Baseline % CADV"). The Exchange believes that the revised threshold criteria are more logical and fairer in that they take into account a change in a Member's volume relative to CADV. The Tape B Step Up Tier would continue to be a credit of $0.0004 per share in addition to the ETP Holder's Tiered or Basic Rate credit(s).

For example, under the proposed Fee Schedule, if the ETP Holder's Tape B Baseline % CADV during May 2013 was 0.10%, the ETP Holder would need to have a Tape B Adding ADV of at least 0.375% in order to qualify for the applicable credit of $0.0004 per share (i.e., 0.10% Tape B Baseline % CADV plus 0.275% of the U.S. Tape B CADV for the billing month).

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[6] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that eliminating the Tape B Adding Tier is reasonable because it has generally not incentivized ETP Holders to provide additional liquidity in Tape B Securities as intended.[7] The Exchange believes that removal of the Tape B Adding Tier is equitable and not unfairly discriminatory because it would be eliminated for all ETP Holders.

The Exchange believes that revising the Tape B Step Up Tier is reasonable because it would make the eligibility requirement consistent with the Exchange's other variable eligibility requirements that also are based on percentage of volume while still incenting ETP Holders and Market Makers to provide liquidity in Tape B Securities. The Exchange believes that the revised threshold criteria for this tier are more logical and fairer in that they take into account a change in a Member's volume relative to CADV. The Exchange believes that the revised Tape B Step Up Tier is equitable and not unfairly discriminating because the $0.0004 credit will remain the same and would continue to be available for all ETP Holders, including Market Makers, on an equal and non-discriminatory basis.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition. For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the removal of the Tape B Adding Tier will not impose a burden on competition because the tier will be removed in its entirety and generally has not encouraged liquidity on the Exchange, as intended. The revised Tape B Step Up Tier will not place a burden on competition because it will apply uniformly to all ETP Holders and Market Makers, and the Exchange does not propose to change the level of the credit.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change promotes a competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2014–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2014–09. This file number should be included on the subject line if email is used.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] *See supra* note 4.

[8] 15 U.S.C. 78f(b)(8).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 15 U.S.C. 78s(b)(2)(B).

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2014–09, and should be submitted on or before March 3, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–02747 Filed 2–7–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71470; File No. SR–Phlx–2014–07]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Membership Process

February 4, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 30, 2014, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 910 to permit an expedited application process for firms that are already approved members of The NASDAQ Stock Market, LLC ("NASDAQ") or NASDAQ OMX BX, Inc. ("BX").

The text of the proposed rule change is attached as Exhibit 5,[3] available on the Exchange's Web site at *nasdaqomxphlx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a PHLX membership rule and provide for an expedited review of applicants seeking to become PHLX member organizations that have already successfully undergone a NASDAQ or BX membership evaluation and are currently members in good standing of NASDAQ or BX. Currently, PHLX Rule 910 provides the qualifications for a Member Organization, including the required terms and conditions. The Exchange is proposing to modify Rule 910 in order to recognize the new member review previously conducted by member regulation when a PHLX applicant has already been approved for membership on NASDAQ or BX.[4] The fundamental membership qualifications are standard across all three domestic exchanges owned by The NASDAQ OMX Group[5] and are all reviewed by NASDAQ member regulation as part of the new member application process. These membership requirements include but are not limited to: Registration as a Broker Dealer with the United States Securities and Exchange Commission, maintaining a pre-determined minimum net capital, qualification of associated persons, maintaining sufficient written supervisory procedures. These and other reviews are considered in each new member review conducted by NASDAQ member regulation or by FINRA on behalf of NASDAQ.[6]

The Exchange is proposing to amend Rule 910 to align PHLX rules with the expedited membership processes that already exist on other exchanges affiliated with PHLX. Specifically, NASDAQ Rule and BX Rule 1013(a)(5)(C) both allow for an expedited membership review process for applicants that are already approved on an affiliated exchange.[7] The membership review for firms that submit a Waive-In Membership Application largely relies [sic] the information previously supplied to NASDAQ and simply reviews any additional new information which has changed or has not yet been evaluated by NASDAQ or by FINRA on behalf of NASDAQ as part of the membership determination. However, the Exchange notes that there are three differences from NASDAQ Rule 1013(a)(5)(C) and BX Rule 1013(a)(5)(c) [sic] and the proposed rule. The first is that NASDAQ and BX also allow FINRA members to qualify for expedited registration. PHLX

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that the text of the proposed rule change is attached to the filing as Exhibit 5, not to this Notice.

[4] NASDAQ and BX are filing separate rule changes which would recognize the membership review conducted by PHLX.

[5] NASDAQ, BX, and PHLX.

[6] FINRA reviews the following membership applications for NASDAQ and BX pursuant to a Regulatory Services Agreement: Waive-in applications for FINRA members that seek to become NASDAQ members; applications for NASDAQ applicants that are not FINRA members; applications for applicants that are simultaneously applying for FINRA and NASDAQ Membership; applications for NASDAQ Options Market Participation; applications for NASDAQ OMX BX; NASDAQ and BX membership applications.

[7] For example, NASDAQ rule 1013(a)(5)(C) states: An applicant that is an approved FINRA or NASDAQ OMX BX, Inc. ("BX") member shall have the option to apply to become a Nasdaq member and to register with Nasdaq all associated persons of the firm whose registrations with the firm are approved with FINRA or BX in categories recognized by Nasdaq rules through an expedited process by submitting a Waive-in Membership Application Form and a Nasdaq Membership Agreement. NASDAQ and BX will file subsequent rule changes to recognize the membership review conducted on behalf of PHLX.

does not plan to include FINRA members in the expedited process.[8] The second is that both NASDAQ and BX have a Short Form Membership application for firms that are already members of the other exchange. PHLX will still require applicants to complete an Organization Membership Application, which must be signed by the Authorized Applicant, the Executive Representative and the Qualifying Permit Holder but will not, as part of the rule change, require the submission of duplicative documentation. The final difference is that the proposed amended rule will still require applicants that require access to the physical trading floor demonstrate knowledge of floor rules and procedures through an on-floor examination.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(5) of the Act[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. NASDAQ's membership department on behalf of PHLX, which performs similar functions for NASDAQ and BX, reviews: Applicant business plans, clearing arrangements, FOCUS reports, organizational charts, and Written Supervisory Procedures for firms applying to any NASDAQ OMX market.[11] These fundamental documents are required for membership to FINRA, as well as for membership on other national securities exchanges.

PHLX believes that the proposed rule change is consistent with Section 6(b)(5) of the Act[12] because it would eliminate the duplicate review for prospective PHLX firms that have already been reviewed and approved for membership by NASDAQ or BX and would require firms only to provide additional information if there had been a change in status from when the firm previously applied to become a member on a NASDAQ OMX exchange. As a consequence, the proposed change will both bring efficiency to the Exchange's membership review process and reduce the burden on applicants that have already been approved for membership on another NASDAQ OMX domestic market by reducing the duplicative information and documentation required to be provided in the process. As a further consequence, the Exchange will be able to focus its regulatory efforts on reviewing any changes or new information that may affect the applicant's eligibility for Exchange membership. Applicants must attest that the information previously provided as part of a new membership review is complete and accurate. Additionally, the proposed expedited review process replicates a process that is currently available to members of NASDAQ and BX under their rules, with the additional requirement that applicants must complete an Organization Membership Application, and to the extent access to the trading floor is sought, pass an on-floor examination. As discussed, PHLX would continue to apply additional scrutiny to applicants in instances where PHLX would be the Designated Examining Authority ("DEA") or where the applicant's proposed business activities required additional review.[13] PHLX is required to conduct additional examinations for firms that which [sic] PHLX is the DEA which includes examining firms for compliance with financial responsibility requirements imposed by the Securities Exchange Act of 1934 and by SEC or SRO rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The expedited review of membership for PHLX applicants will not impose any burden on competition and will remove unnecessary burdens that currently exist for NASDAQ and BX firms when seeking PHLX membership. Currently, existing NASDAQ or BX firms that seek to become PHLX member firms are required to undergo a duplicative membership review in order to add a PHLX membership. This redundant review would not exist if they sought membership on one of the other NASDAQ exchanges. The Exchange seeks this rule modification in order to harmonize the rules and minimize duplicative membership reviews across all NASDAQ OMX exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[8] NASDAQ and BX recognize the FINRA membership approval because the membership rules are the same and are covered under a 17d–2 agreement. PHLX does not plan to recognize FINRA's approval because of the slight differences in membership rules but will review this issue if PHLX membership rules are modified and become more closely aligned with NASDAQ and BX rules.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] FINRA conducts the new member application review for NASDAQ and BX pursuant to a 17d–2 agreement and Regulatory Services Agreement. These application reviews are administered by FINRA and subject to NASDAQ's final review and decision.

[12] *Supra* note 8 [sic].

[13] Prospective members seeking to conduct business on the PHLX trading floor requires [sic] a particularized understanding of the PHLX trading floor rules. Additionally, applicants for which PHLX will be the DEA are required to file the following material; Branch Office Disclosure Form, FOCUS filings, Verification of an error account, Proprietary Account of Introducing Broker Dealer Agreement, Confirmation of U4 registrations, Copy of Joint Back Office Agreements (if applicable), Notification of Applicant's intent to use Electronic Storage Media for maintaining and storing records.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2014–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2014–07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2014–07 and should be submitted on or before March 3, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–02745 Filed 2–7–14; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71473; File No. SR–NASDAQ–2014–009]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Proposed Rule Change Relating to the Listing and Trading of the Shares of the First Tactical High Yield ETF of First Trust Exchange-Traded Fund IV

February 4, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on January 22, 2014, The NASDAQ Stock Market LLC ("Nasdaq" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to list and trade the shares of the First Trust Tactical High Yield ETF (formerly known as the First Trust High Yield Long/Short ETF) (the "Fund") of First Trust Exchange-Traded Fund IV (the "Trust") under Nasdaq Rule 5735 ("Managed Fund Shares"). The shares of the Fund are collectively referred to herein as the "Shares."

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/*, at Nasdaq's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item III below, and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to reflect changes to the means of achieving the investment objectives of the Fund.[3] The Commission has approved the listing and trading of Shares under NASDAQ Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange.[4] The Exchange believes the proposed rule change reflects no significant issues not previously addressed in the Prior Release. The Fund is an actively managed exchange-traded fund ("ETF"). The Shares are offered by the Trust, which was organized as a Massachusetts business trust on September 15, 2010. The Trust, which is registered with the Commission as an investment company, has filed a registration statement on Form N–1A ("Registration Statement") relating to the Fund with the Commission.[5] First Trust Advisors L.P. ("First Trust Advisors") is the investment adviser ("Adviser") to the Fund.

The Exchange now proposes two modifications to the description of the measures the Adviser would utilize to implement the Fund's investment objectives.[6] The Adviser seeks to make the modifications described below to certain representations in the Prior Release.

First, the Exchange proposes to modify a representation reflected in the Prior Release by increasing the percentage of the Fund's net assets that may be invested in bank loans. In

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 68972 (February 22, 2013), 78 FR 13721 (February 28, 2013) (SR–NASDAQ–2012–147) (order approving listing and trading of First Trust High Yield Long/Short ETF).

[4] The Commission approved NASDAQ Rule 5735 (formerly Nasdaq Rule 4420(o)) in Securities Exchange Act Release No. 57962 (June 13, 2008), 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). The Commission previously approved the listing and trading of the Shares of the Fund. *See* Securities Exchange Act Release No. 68972 (February 22, 2013), 78 FR 13721 (February 28, 2013) (SR–NASDAQ–2012–147) ("Prior Order"). *See also* Securities Exchange Act Release No. 68581 (January 4, 2013), 78 FR 2295 (January 10, 2013) (SR–NASDAQ–2012–147) ("Prior Notice," and together with the Prior Order, the "Prior Release").

[5] *See* Post-Effective Amendment No. 23 to Registration Statement on Form N–1A for the Trust, dated February 8, 2013 (File Nos. 333–174332 and 811–22559). On February 27, 2013, July 3, 2013 and September 4, 2013, the Trust made filings under Rule 497 under the Securities Act of 1933 (collectively, the "497 Filings") for the Fund. The descriptions of the Shares and the Fund contained herein are based, in part, on information in the Registration Statement and the 497 Filings. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (the "1940 Act"). *See* Investment Company Act Release No. 30029 (April 10, 2012) (File No. 812–13795) (the "Exemptive Order").

[6] The Adviser represents that it has managed and will continue to manage the Fund in the manner described in the Prior Release, and will not implement the changes, as described herein, until the instant proposed rule change is operative.

accordance with the Prior Release, the Fund may invest up to 15% of its net assets in "bank loans," which, as described in the Prior Release, may include loan interests that are not secured by any specific collateral of the borrower, loan interests that have a lower than first lien priority on collateral of the borrower, loans to foreign borrowers, loans in foreign currencies and other loans with characteristics that the Adviser believes qualify as bank loans. Going forward, the Exchange proposes that the Fund would be permitted to invest up to 40% of its net assets in bank loans.

The proposed change is intended to provide greater flexibility to the Adviser as it tactically allocates proceeds across the high yield debt market and across the debt capital structure of select companies. Additionally, this proposed change would provide the Adviser with increased flexibility to manage the Fund's duration in periods of rising rates. The Adviser represents that the Fund would continue to invest 85% or more of the portfolio in securities that the Adviser deems to be sufficiently liquid at the time of investment. In addition, consistent with the Prior Release, the Adviser would continue to monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained.

The Exchange also proposes to delete a representation reflected in the Prior Release, which states that consistent with the Exemptive Order, the Fund would not invest in options contracts, futures contracts or swap agreements (the "Derivatives Representation").

On December 6, 2012, the staff of the Commission's Division of Investment Management ("Division") issued a no-action letter ("No-Action Letter") relating to the use of derivatives by actively-managed ETFs.[7] The No-Action Letter noted that, in March of 2010, the Commission announced in a press release that the staff was conducting a review to evaluate the use of derivatives by mutual funds, ETFs, and other investment companies and that, pending completion of this review, the staff would defer consideration of exemptive requests under the 1940 Act relating to, among others, actively-managed ETFs that would make significant investments in derivatives.

The No-Action Letter stated that the Division staff will no longer defer consideration of exemptive requests under the 1940 Act relating to actively-managed ETFs that make use of derivatives provided that they include representations to address some of the concerns expressed in the Commission's March 2010 press release. These representations are: (i) That the ETF's board periodically will review and approve the ETF's use of derivatives and how the ETF's investment adviser assesses and manages risk with respect to the ETF's use of derivatives; and (ii) that the ETF's disclosure of its use of derivatives in its offering documents and periodic reports is consistent with relevant Commission and staff guidance. The No-Action Letter stated that the Division would not recommend enforcement action to the Commission under sections 2(a)(32), 5(a)(1), 17(a), 22(d), and 22(e) of the 1940 Act, or rule 22c–1 under the 1940 Act if actively-managed ETFs operating in reliance on specified orders (which include the Trust's Exemptive Order[8]) invest in options contracts, futures contracts or swap agreements provided that they comply with the representations stated in the No-Action Letter, as noted above.

In view of the No-Action Letter, the Exchange is proposing to delete the Derivatives Representation and to permit the Fund to use "Derivative Instruments," as defined and described below.

The Exchange now proposes that to pursue its investment objectives it be permitted to invest in interest rate swaps, total return swaps, credit default swaps, options, options on futures contracts, futures contracts, forward contracts, structured notes, non-U.S. currency swaps, currency options, forward currency contracts and non-deliverable forward currency contracts (collectively, "Derivative Instruments"). The use of Derivative Instruments may allow the Fund to seek to enhance return, to hedge some of the risks of its investments in securities, as a substitute for a position in an underlying asset, to reduce transaction costs, to maintain full market exposure (which means to adjust the characteristics of its investments to more closely approximate those of the markets in which it invests), to manage cash flows, to preserve capital or to manage its foreign currency exposures.[9]

The Fund generally expects that no more than 30% of the value of the Fund's net assets would be invested in Derivative Instruments; however, there would be no limitation on the Fund's investments in Derivative Instruments to be used by the Fund solely for hedging purposes.[10]

The Prior Release stated that the Fund's investments would not be used to enhance leverage. In view of the Exchange's proposal to permit the Fund to use Derivative Instruments, the Fund's investments in Derivative Instruments could potentially be used to enhance leverage. However, the Fund's investments in Derivative Instruments would be consistent with the Fund's investment objectives and would not be used to seek to achieve a multiple or inverse multiple of an index.

Further, the Fund's investments in Derivative Instruments would be valued at market value or, in the absence of market value with respect to any Derivative Instrument, at fair value in accordance with valuation procedures adopted by the Trust's Board of Trustees and in accordance with the 1940 Act.

Investments in Derivative Instruments would be made in accordance with the 1940 Act and consistent with the Fund's investment objectives and policies. The Fund would comply with the regulatory requirements of the Commission to maintain assets as "cover," maintain segregated accounts, and/or make margin payments when it takes positions in Derivative Instruments involving obligations to third parties (*i.e.*, instruments other than purchase options). If the applicable guidelines prescribed under the 1940 Act so require, the Fund would earmark or set aside cash, U.S. government securities, high grade liquid debt securities and/or other liquid assets permitted by the Commission in a segregated custodial account in the amount prescribed.[11]

[7] *See* No-Action Letter dated December 6, 2012 from Elizabeth G. Osterman, Associate Director, Office of Exemptive Applications, Division of Investment Management.

[8] *See* footnote 5.

[9] In particular, the Adviser contemplates that the Fund would sell futures on U.S. Treasury obligations as an alternative to engaging in short sales to gain short exposure to the U.S. Treasury market.

[10] The Fund will limit its direct investments in futures, options on futures and swaps to the extent necessary for the Adviser to claim the exclusion from regulation as a "commodity pool operator" with respect to the Fund under Rule 4.5 promulgated by the Commodity Futures Trading Commission ("CFTC"), as such rule may be amended from time to time. Under Rule 4.5 as currently in effect, the Fund will limit its trading activity in futures, options on futures and swaps (excluding activity for "bona fide hedging purposes," as defined by the CFTC) such that it will meet one of the following tests: (i) aggregate initial margin and premiums required to establish its futures, options on futures and swap positions will not exceed 5% of the liquidation value of the Fund's portfolio, after taking into account unrealized profits and losses on such positions; or (ii) aggregate net notional value of its futures, options on futures and swap positions will not exceed 100% of the liquidation value of the Fund's portfolio, after taking into account unrealized profits and losses on such positions.

[11] With respect to guidance under the 1940 Act, *see* 15 U.S.C. 80a-18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128

Continued

The Fund would include appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of the Fund, including the Fund's use of Derivative Instruments, may give rise to leverage, causing the Fund to be more volatile than if it had not been leveraged.[12]

Based on the above, the Exchange seeks this modification to reflect the No-Action Letter. The Adviser believes that the ability to invest in Derivative Instruments would provide it with additional flexibility to meet the Fund's investment objectives.

The Fund would continue to comply with all initial and continued listing requirements under NASDAQ Rule 5735.

The Adviser represents that there is no change to the Fund's investment objectives. Except for the changes proposed herein, all other facts presented and representations made in the Rule 19b-4 [13] filings underlying the Prior Release remain unchanged.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [14] in general and Section 6(b)(5) of the Act [15] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule changes are designed to prevent fraudulent and manipulative acts and practices in that the Shares would continue to be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NASDAQ Rule 5735. The first proposed rule change would permit the Fund to invest up to 40% (rather than up to 15%) of its net assets in bank loans, however, the Adviser represents that the Fund would continue to invest 85% or more of its portfolio in securities that the Adviser deems to be sufficiently liquid at the time of investment and would continue to monitor portfolio liquidity on an ongoing basis.

The second proposed rule change is consistent with the No-Action Letter and would permit the Fund to invest in Derivative Instruments. The Fund generally expects that no more than 30% of the value of the Fund's net assets would be invested in Derivative Instruments; however, there would be no limitation on the Fund's investments in Derivative Instruments to be used by the Fund solely for hedging purposes. The Fund's investments in Derivative Instruments would be consistent with the Fund's investment objectives and would not be used to seek to achieve a multiple or inverse multiple of an index. Investments in Derivative Instruments would be made in accordance with the 1940 Act and would be consistent with the Fund's investment objectives and policies.

The proposed rule changes are designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Adviser represents that there is no change to the Fund's investment objectives. The Adviser represents that the purpose of the proposed changes is to provide it with greater flexibility in meeting the Fund's investment objectives by permitting (1) the Fund to invest a greater portion of its net assets in bank loans and (2) the Fund to invest a portion of its net assets in Derivative Instruments. In addition, consistent with the Prior Release, the net asset value ("NAV") per Share would continue to be calculated daily and the NAV and "Disclosed Portfolio" (as defined in the Prior Release) would be made available to all market participants at the same time.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an actively managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

As noted above, the additional flexibility to be afforded to the Adviser under the proposed rule change is intended to enhance the Adviser's ability to meet the Fund's investment objectives. Further, as noted in the Prior Release, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via the Intermarket Surveillance Group ("ISG") from other exchanges that are members of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as indicated in the Prior Release, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value (as defined in the Prior Release), the Disclosed Portfolio (as defined in the Prior Release), and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days after publication (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2014–009 on the subject line.

(April 27, 1979); *Dreyfus Strategic Investing*, Commission No-Action Letter (June 22, 1987); *Merrill Lynch Asset Management, L.P.*, Commission No-Action Letter (July 2, 1996).

[12] To mitigate leveraging risk, the Fund will segregate or "earmark" liquid assets or otherwise cover the transactions that may give rise to such risk.

[13] 17 CFR 240.19b-4.

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(5).

[16] The Commission notes that Nasdaq included the following additional statement in its Form 19b–4: "The Exchange believes the proposed rule change will permit the Adviser additional flexibility in achieving the Fund's investment objectives, thereby offering investors additional investment options."

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASDAQ–2014–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site *http://www.sec.gov/rules/sro.shtml*. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2014–009 and should be submitted on or before March 3, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–02746 Filed 2–7–14; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71485; File No. S7–27–11]

Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with the Revision of the Definition of "Security" to Encompass Security-Based Swaps, and Request for Comment

I. Introduction

The Securities and Exchange Commission ("Commission") is extending certain temporary exemptive relief contained in a prior Commission order ("Exchange Act Exemptive Order")[1] in connection with the revision of the Exchange Act definition of "security" to encompass security-based swaps. These temporary exemptions were provided by the Commission on July 1, 2011 and are set to expire on February 11, 2014 ("Expiring Temporary Exemptions").

As described in more detail below, the Commission is extending the expiration date for the Expiring Temporary Exemptions. Specifically, for those Expiring Temporary Exemptions that are not directly linked to pending security-based swap rulemakings, the Commission is extending the expiration date until the earlier of such time as the Commission issues an order or rule determining whether any continuing exemptive relief is appropriate for security-based swap activities with respect to any of these Exchange Act provisions or until three years following the effective date of this Order. For each Expiring Temporary Exemption that is related to pending security-based swap rulemakings, the Commission is extending the expiration date until the compliance date for the related security-based swap-specific rulemaking.

The approach for extending the exemptions related to security-based swap rulemakings reflected in this Order is intended to facilitate a timely phased-in determination regarding the application of the relevant provisions of the Exchange Act to security-based swaps based on the development of the relevant rules mandated by the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act")[2] as the Commission moves toward finalizing those rules. This approach also provides the Commission flexibility while Dodd-Frank Act rulemaking is still in progress to determine whether continuing relief should be provided for any Exchange Act provisions that are not directly linked to specific security-based swap rulemaking.

II. Discussion

A. Background

Title VII of the Dodd-Frank Act amended the Exchange Act definition of "security" to expressly encompass security-based swaps.[3] The expansion of the definition of the term "security" has changed the scope of the Exchange Act regulatory provisions that apply to security-based swaps and has raised certain complex questions that require further consideration.

On July 1, 2011, the Commission issued an order granting temporary exemptive relief from compliance with certain provisions of the Exchange Act in connection with the revision of the Exchange Act definition of "security" to encompass security-based swaps.[4] The overall approach of the Exchange Act Exemptive Order was directed toward maintaining the *status quo* during the implementation process for the Dodd-Frank Act, by preserving the application of particular Exchange Act requirements that were already applicable in connection with instruments that became "security-based swaps" following the effective date of the Dodd-Frank Act,[5] but deferring the applicability of additional Exchange Act requirements in connection with those instruments explicitly being defined as "securities" as of the effective date.[6] The Expiring Temporary Exemptions generally provide for the following exemptions from Exchange Act: (a) Temporary exemptions in connection with security-based swap activity by certain "eligible contract participants"; and (b) temporary exemptions specific to security-based swap activities by registered brokers and dealers.[7] These Expiring Temporary Exemptions[8] are

[1] *See* Order Granting Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with the Pending Revisions of the Definition of "Security" to Encompass Security-Based Swaps, Exchange Act Release No. 64795 (Jul. 1, 2011), 76 FR 39927 (Jul. 7, 2011) ("Exchange Act Exemptive Order").

[2] The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124, Stat. 1376 (2010).

[3] Exchange Act Section 3(a)(10), 15 U.S.C. 78c(a)(10), as revised by Section 761(a)(2) of the Dodd-Frank Act.

[4] *See* Exchange Act Exemptive Order.

[5] *Id.* The Title VII amendments of the Dodd-Frank Act generally became effective on July 16, 2011 (360 days after the enactment of the Dodd-Frank Act).

[6] *See* Exchange Act Exemptive Order at 5–6.

[7] *See* Exchange Act Exemptive Order at 39–44.

[8] The Exchange Act Exemptive Order provided a temporary exemption from Sections 5 and 6 of the Exchange Act until the earliest compliance date set forth in any of the final rules regarding registration of security-based swap execution facilities. The Exchange Act Exemptive Order also provided that

Continued

currently scheduled to expire on February 11, 2014.[9]

To date, the Commission has proposed substantially all of the rules related to the new regulatory regime for derivatives under Title VII and has begun the process of adopting these rules.[10] Keeping with the Dodd-Frank Act's stated objective of promoting financial stability in the U.S. financial system, the Commission has expressed its intent to move forward deliberatively in implementing the requirements of the Dodd-Frank Act, while minimizing unnecessary disruption and costs to the markets.[11] Among the rules for this new regulatory framework that the Commission has proposed are rules relating to (i) capital, margin, and segregation requirements for security-based swap dealers and major security-based swap participants,[12] (ii) security-based swap trade acknowledgement,[13] and (iii) security-based swap execution facilities registration requirements.[14] In addition, the Commission has also been mandated by the Dodd-Frank Act to promulgate recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants.[15]

B. Extension of Temporary Exemptions

The Commission believes it is necessary or appropriate in the public interest, and consistent with the protection of investors to extend the Expiring Temporary Exemptions in order to avoid any potential market disruption stemming from the application of existing rules to security-based swap activities. Although the Commission is making significant progress in establishing and finalizing the new regulatory regime for securities-based swaps, key issues and questions regarding the application of the federal securities laws to security-based swaps remain unresolved. However, because the Commission has proposed substantially all of the rules related to the new regulatory regime for derivatives under Title VII, the Commission is able to better calibrate the need for extensions of the Expiring Temporary Exemptions based on how those exemptions relate to ongoing rulemaking. Accordingly, under this approach an extension of the Expiring Temporary Exemptions will provide the Commission with additional time to consider the potential impact of the revision of the Exchange Act definition of "security" on the scope of Exchange Act provisions applicable to security-based swaps, as well as the appropriateness of applying certain Exchange Act provisions to security-based swap activities in light of the Commission's continuing rulemaking efforts.[16]

While the Commission is generally extending the Expiring Temporary Exemptions, it is refining the applicable expiration dates for these exemptions by (1) extending the expiration date of certain Expiring Temporary Exemptions that are generally not directly related to specific security-based swap rulemakings until the earlier of such time that the Commission issues an order or rule determining whether any continuing exemptive relief is appropriate for security-based swap activities with respect to any of these Exchange Act provisions or until three years following the effective date of this Order, and (2) extending the expiration date of other Expiring Temporary Exemptions that are directly related to specific security-based swap rulemakings, until the compliance date for the relevant security-based swap rulemaking.[17]

This approach recognizes the continuing development of the new regulatory regime for security-based swaps and takes into consideration the interrelation of certain existing Exchange Act provisions with this new regime. Specifically, the Commission believes it is necessary or appropriate in the public interest, and consistent with the protection of investors for the subset of Expiring Temporary Exemptions that are related to certain ongoing rulemakings to be addressed within any such rulemakings that are finalized in order to determine what, if any, exemptions would be appropriate based on the structure of the regulatory framework. The expiration dates of this subset of Expiring Temporary Exemptions will be extended until they are addressed within any relevant rulemakings relating to: (i) Capital, margin, and segregation requirements

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no security-based swap contract entered into on or after July 16, 2011 shall be void or considered voidable by reason of Section 29(b) of the Exchange Act because any person that is a party to the contract violated a provision of the Exchange Act for which the Commission has provided exemptive relief in the Exchange Act Exemptive Order, until such time as the underlying exemptive relief expires. This extension order does not affect either of these expiration dates.

[9] *See* Further Definition of "Swap," "Security-Based Swap," and "Security-Based Swap Agreement"; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, Exchange Act Release No. 67453 (Jul. 18, 2012), 77 FR 48207 (Aug. 13, 2012) ("Product Definitions Adopting Release") (extending the expiration date of the Expiring Temporary Exemptions to February 11, 2013) and Order Extending Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with the Revision of the Definition of "Security" to Encompass Security-Based Swaps, and Request for Comment, Exchange Act Release No. 68864 (Feb. 7, 2013), 78 FR 10218 (Feb. 13, 2013) ("Extension Release") (extending the expiration date to February 11, 2014). Before issuing the Extension Release, the Commission received a request to extend the Expiring Temporary Exemptions from market participants, citing concerns that key issues and questions regarding the application of the federal securities laws remained unresolved and continuing concerns about the potential for unnecessary disruption to the security-based swap market. *See* SIFMA Request for Extension of the Expiration Date of the SEC's Exchange Act Exemptive Order and SBS Interim final Rules (Dec. 20, 2012) ("SIFMA Extension Request"), which is available at *http://www.sec.gov/comments/s7-27-11/s72711-12.pdf.*

[10] *See* Statement of General Policy on the Sequencing of the Compliance Dates for Final Rules Applicable to Security-Based Swaps Adopted Pursuant to the Securities Exchange Act of 1934 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, Exchange Act Release No. 67177 (Jun. 11, 2012), 77 FR 35625 (Jun. 14, 2012). *See also* Reopening of Comment Periods for Certain Rulemaking Releases and Policy Statement Applicable to Security-Based Swaps Proposed Pursuant to the Securities Exchange Act of 1934 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, Exchange Act Release No. 69491 (May 1, 2013), 78 FR 30800 (May 23, 2013) ("Reopening Release") which reopened the comment period until July 22, 2013. *See also e.g.* Product Definitions Adopting Release; Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant" and "Eligible Contract Participant", Exchange Act Release No. 66868 (Apr. 27, 2012), 77 FR 30596 (May 23, 2012); Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies; Technical Amendments to Rule 19b-4 and Form 19b-4 Applicable to all Self-Regulatory Organizations, Exchange Act Release No. 67286 (Jun. 28, 2012), 88 FR 41602 (Jul. 13, 2012); Clearing Agency Standards, Exchange Act Release No. 68080 (Oct. 22, 2012), 77 FR 66219 (Nov. 2, 2012).

[11] *See* Exchange Act Exemptive Order.

[12] *See* Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital Requirements for Broker-Dealers, Exchange Act Release No. 68071 (Oct. 18, 2012), 77 FR 70213 (Nov. 23, 2012) ("Security-Based Swap Capital and Margin Rules"). *See also* Reopening Release.

[13] *See* Trade Acknowledgement and Verification of Security-Based Swap Transactions, Exchange Act Release No. 63727 (Jan. 14, 2011), 76 FR 3859 (Jan. 21, 2011) ("Trade Acknowledgement Rule"). *See also* Reopening Release.

[14] *See* Registration and Regulation of Security-Based Swap Execution Facilities, Exchange Act Release No. 63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011) ("Security-Based Swap Execution Facility Rules"). *See also* Reopening Release.

[15] *See* 15 U.S.C. 78o–10(f).

[16] This is also consistent with previous requests to extend the Expiring Temporary Exemptions. *See* SIFMA Extension Request. The Commission has also received a request for certain permanent exemptions upon the expiration of the exemptions contained in the Exchange Act Exemptive Order. *See* SIFMA SBS Exemptive Relief Request (Dec. 5, 2011), which is available at *http://www.sec.gov/comments/s7-27-11/s72711-10.pdf.*

[17] Subsequent to the issuance of the Exchange Act Exemptive Order, the Commission adopted rules related to certain requirements applicable to municipal advisors. *See* Registration of Municipal Advisors, Exchange Act Release No. 70462 (Sep. 20, 2013), 78 FR 67467 (Nov. 12, 2013). The temporary exemptions provided in this order do not apply to these recently adopted rules.

for security-based swap dealers and major security-based swap participants, (ii) recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants, (iii) security-based swap trade acknowledgement rules, and/or (iv) registration requirements for security-based swap execution facilities.

In addition, with respect to the subset of Expiring Temporary Exemptions that are not directly related to specific security-based swap rulemakings, the Commission believes it would be appropriate for these exemptions to continue for three years or until such time as the Commission issues an order or rule determining whether any continuing exemption is applicable to any of these provisions. This approach is designed to limit the potential for market disruptions. Moreover, this approach is designed to provide sufficient time for the Commission to explore and potentially develop an appropriate framework for regulating security based swap activities and to provide sufficient time for public input regarding any such potential framework. Accordingly, pursuant to its authority under Section 36 of the Exchange Act,[18] the Commission believes it is necessary or appropriate in the public interest, and consistent with the protection of investors to extend the Expiring Temporary Exemptions that are not related to specific securities-based swap rulemakings until the earlier of the time that the Commission issues an order or rule determining whether continuing exemptive relief is appropriate or until three years after the effective date of this Order.

The Commission is also, pursuant to its authority under Section 36, extending the below outlined Expiring Temporary Exemptions, until the earliest compliance dates established in applicable rulemakings.

1. Expiring Temporary Exemptions Relating to Security-Based Swap Capital and Margin Rules

The Commission is extending the Expiring Temporary Exemptions for the following Exchange Act provisions until the earliest compliance date set forth in any final security-based swap capital, margin, and segregation rules:[19]

- Section 7,[20] regarding the margin requirements for broker-dealers; and Regulation T,[21] a Federal Reserve Board regulation regarding broker-dealer extension of credit.[22]
- Section 15(c)(3),[23] which provides the Commission with rulemaking authority in connection with broker-dealer financial responsibility; Exchange Act Rule 15c3–1,[24] including Appendices A–G (Exchange Act Rules 15c3–1a through 15c3–1g)[25] regarding net capital requirements for brokers and dealers; Exchange Act Rule 15c3–3,[26] including 15c3–3a,[27] regarding broker-dealer reserves and custody of securities; and Exchange Act Rule 15c3–4,[28] regarding internal risk management control systems for OTC derivatives dealers.[29]

2. Expiring Temporary Exemptions Relating to Security-Based Swap Recordkeeping Rules

The Commission is extending the Expiring Temporary Exemptions for the following Exchange Act provisions until the earliest compliance date set forth in any final rules regarding recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants:[30]

- Section 17(a),[31] regarding broker-dealer obligations to make, keep and furnish information; Section 17(b),[32] regarding broker-dealer records subject to examination; Exchange Act Rules 17a–3 through 17a–5,[33] regarding records to be made and preserved by broker-dealers and reports to be made by broker-dealers; Exchange Act Rule 17a–11,[34] regarding notifications that broker-dealers are required to make; and Exchange Act Rule 17a–13,[35] regarding quarterly security counts to be made by certain exchange members and broker-dealers.[36]

3. Expiring Temporary Exemptions Relating to Broker-Dealer Registration Requirements

The Commission is extending the Expiring Temporary Exemptions that relate to the registration requirements under section 15(a)(1) of the Exchange Act[37] and the other requirements of the Exchange Act and the rules and regulations thereunder that apply to a broker or dealer that is not registered with the Commission[38] until the later of the compliance dates set forth in (i) any final rules regarding capital, margin and segregation requirements for security-based swap dealers and major security-based swap participants[39] or (ii) any final rules regarding recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants.[40]

[18] 15 U.S.C. 78mm. Section 36 of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt, by rule, regulation, or order any person, security, or transaction (or any class or classes of persons, securities, or transactions) from any provision or provisions of the Exchange Act or any rule or regulation thereunder, to the extent such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

[19] In late 2012, the Commission proposed the Security-Based Swap Capital and Margin Rules. The proposed rules, if adopted, will clarify how certain Exchange Act provisions relating to the capital, margin, and segregation requirements of registered broker-dealers will apply to the security-based swap activities of registered broker-dealers.

[20] 15 U.S.C. 78g.

[21] 12 CFR 220.1 *et seq.*

[22] Under the approach of preserving the *status quo*, the Exchange Act Exemptive Order provided registered broker-dealers a limited exemption from Section 7(c) and Regulation T only to the extent that these provisions did not apply to the broker-dealer's security-based swap positions or activities prior to expansion of the definition of "security" to include security-based swaps.

[23] 15 U.S.C. 78o(c)(3).

[24] 17 CFR 240.15c3–1.

[25] 17 CFR 240.15c3–1a through 15c3–1g.

[26] 17 CFR 240.15c3–3.

[27] 17 CFR 240.15c3–3a.

[28] 17 CFR 240.15c3–4.

[29] Under the approach of preserving the *status quo*, the Exchange Act Exemptive Order provided registered broker-dealers a limited exemption from Section 15(c)(3) and Rules 15c3–1 and 15c3–3 only to the extent that these provisions did not apply to the broker-dealer's security-based swap positions or activities prior to expansion of the definition of "security" to include security-based swaps. However, the limited exemption from Rule 15c3–3 is not available for registered broker-dealers' activities and positions related to cleared security-based swaps, to the extent that a broker-dealer is a member of a clearing agency that functions as a central counterparty for security-based swaps, and holds customer funds or securities in connection with cleared security-based swaps.

[30] *See* 15 U.S.C. 78o–10(f).

[31] 15 U.S.C. 78q(a).

[32] 15 U.S.C. 78q(b).

[33] 17 CFR 240.17a–3 through 17a–5.

[34] 17 CFR 240.17a–11.

[35] 17 CFR 240.17a–13.

[36] Under the approach of preserving the *status quo*, the Exchange Act Exemptive Order provided registered broker-dealers a limited exemption from Sections 17(a) and (b), Rules 17a–3 through 17a–5, and Rule 17a–13 only to the extent that these provisions did not apply to the broker-dealer's security-based swap positions or activities prior to expansion of the definition of "security" to include security-based swaps.

[37] 15 U.S.C. 78o(a)(1).

[38] The Exchange Act Exemptive Order excluded from the exemption (1) the "broker" registration requirements of Section 15(a)(1) (and other Exchange Act requirements that apply to a non-registered broker) for broker activities involving security-based swaps by persons that are members of a clearing agency that functions as a central counterparty for security-based swaps and that holds customer funds and securities in connection with security-based swaps; and (2) the "dealer" registration requirements of Section 15(a)(1) (and other Exchange Act requirements that apply to a non-registered dealer) for security-based swaps dealing activities unless those activities involve counterparties that meet the definition of an eligible contract participant.

[39] *See supra* note 19.

[40] *See* 15 U.S.C. 78o–10(f).

4. Expiring Temporary Exemption Relating to Trade Acknowledgement Rule

The Commission is extending the Expiring Temporary Exemption for Exchange Act Rule 10b–10,[41] regarding confirmation of transactions, until the earliest compliance date set forth in any final rules regarding trade acknowledgement and verification of security-based swap transactions.[42]

5. Expiring Temporary Exemption Relating to Regulation ATS

The Commission is extending the Expiring Temporary Exemption for Regulation ATS,[43] regarding the regulatory requirements that apply to alternative trading systems, until the earliest compliance date set forth in any final rules regarding the registration of the security-based swap execution facilities.[44]

III. Solicitation of Comments

The Commission believes that it would be useful to continue to provide interested parties the opportunity to comment on any aspect of the temporary exemptions contained in the Exchange Act Exemptive Order, this Order extending the Expiring Temporary Exemptions, and any additional relief that should be granted upon the expiration of the extension of the Expiring Temporary Exemptions, including:

1. Is the distinction between whether an exemption is "not directly linked" to any security-based swap rulemaking or is "related" to security-based swap rulemaking appropriate in connection with the extension of the Expiring Temporary Exemptions? Are there additional Expiring Temporary Exemptions that should be linked to the adoption of any specific security-based swap rulemakings?

2. Is additional exemptive relief necessary or appropriate in light of the ongoing implementation of the Dodd-Frank Act? Are there particular Exchange Act provisions, for which relief has already been granted, that do not warrant a continuing exemption? Are there particular Exchange Act provisions, for which relief has not previously been granted, that warrant exemptions?

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/exorders.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number S7–27–11 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F St. NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–27–11. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/exorders.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F St. NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

IV. Conclusion

It Is Hereby Ordered, pursuant to Section 36 of the Exchange Act, that the Expiring Temporary Exemptions contained in the Exchange Act Exemptive Order in connection with the revisions of the Exchange Act definition of "security" to encompass security-based swaps are extended until the earlier of three years following the effective date of this Order or, until such time that the Commission issues an order or rule determining whether continuing exemptive relief is appropriate for security-based swap activities with respect to any of the Expiring Temporary Exemptions, except as set forth below:

(a) The following exemptions are extended until the compliance date set forth in any final rules regarding capital, margin and segregation requirements for security-based swap dealers and major security-based swap participants:

(1) Section 7;
(2) Section 15(c)(3);
(3) Regulation T, 12 CFR 220.1 *et seq.;*
(4) Rule 15c3–1;
(5) Rule 15c3–3; and
(6) Rule 15c3–4.

(b) The following exemptions are extended until the compliance date set forth in any final rules regarding recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants:

(1) Section 17(a);
(2) Section 17(b);
(3) Rule 17a–3;
(4) Rule 17a–4;
(5) Rule 17a–5;
(6) Rule 17a–11; and
(7) Rule 17a–13.

(c) The exemption pertaining to Rule 10b-10 is extended until the compliance date set forth in any final rules regarding trade acknowledgement and verification of security-based swap transactions.

(d) The exemption pertaining to Regulation ATS, 17 CFR 242.300 *et seq.,* is extended until the compliance date set forth in any final rules regarding the registration of security-based swap execution facilities.

(e) The following exemptions are extended until the later of the compliance dates set forth in (i) any final rules regarding capital, margin and segregation requirements for security-based swap dealers and major security-based swap participants and (ii) any final rules regarding recordkeeping and reporting requirements for security-based swap dealers and major security-based swap participants:

(1) Exemptions pertaining to the "broker" registration requirements of section 15(a)(1) of the Exchange Act, and the other requirements of the Exchange Act and the rules and regulations thereunder that apply to a broker that is not registered with the Commission, solely in connection with broker activities involving security-based swaps, and

(2) Exemptions pertaining to the "dealer" registration requirements of section 15(a)(1) of the Exchange Act, and the other requirements of the

[41] 17 CFR 240.10b–10.

[42] In January 2011, the Commission proposed the Trade Acknowledgement Rule which would govern the way in which certain security-based swap transactions would be acknowledged and verified by the parties. Under the proposed rule, security-based swap dealers and major security-based swap participants would have to provide to their counterparties a trade acknowledgement detailing information specific to the transaction. The Commission also proposed a limited exemption from the requirements of Exchange Act Rule 10b–10 for security-based swap dealers and major security-based swap participants that confirm their security-based swap transactions in compliance with the Trade Acknowledgement Rule. The proposed exemption is intended to avoid the duplicative requirements of having to comply with both Exchange Act Rule 10b–10 and the proposed Trade Acknowledgement Rule.

[43] 17 CFR 242.300 *et seq.*

[44] In February 2011, the Commission proposed the Security-Based Swap Execution Facility Rules which, if adopted, will create a registration framework for security-based swap execution facilities, as well as, establish rules governing these entities.

Exchange Act and the rules and regulations thereunder that apply to a dealer that is not registered with the Commission, solely in connection with dealing activities involving security-based swaps with counterparties that meet the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2014–02834 Filed 2–7–14; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13877]

West Virginia Disaster #WV–00034 Declaration of Economic Injury

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of West Virginia, dated 01/29/2014.

Incident: Chemical Spill that contaminated the water supply.

Incident Period: 01/09/2014 through 01/17/2014.

Effective Date: 01/29/2014.

EIDL Loan Application Deadline Date: 10/29/2014.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Boone, Kanawha, Putnam.

Contiguous Counties:

West Virginia: Cabell, Clay, Fayette, Jackson, Lincoln, Logan, Mason, Nicholas, Raleigh, Roane, Wyoming.

The Interest Rates are:

	Percent
Businesses And Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.625

The number assigned to this disaster for economic injury is 138770.

The State which received an EIDL Declaration # is West Virginia.

(Catalog of Federal Domestic Assistance Number 59002)

Dated: January 29, 2014.

Jeanne Hulit,

Acting Administrator.

[FR Doc. 2014–02705 Filed 2–7–14; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13880 and #13881]

Vermont Disaster #VT–00029

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA–4163–DR), dated 01/29/2014.

Incident: Severe Winter Storms.

Incident Period: 12/20/2013 through 12/26/2013.

Effective Date: 01/29/2014.

Physical Loan Application Deadline Date: 03/31/2014.

Economic Injury (EIDL) Loan Application Deadline Date: 10/29/2014.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/29/2014, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Caledonia, Chittenden, Essex, Franklin, Grand Isle, Lamoille, Orleans.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 13880B and for economic injury is 13881B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2014–02707 Filed 2–7–14; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Audit and Financial Management Advisory Committee, Re-Establishment

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of re-establishment of Audit and Financial Management Advisory Committee.

SUMMARY: Pursuant to the Federal Advisory Committee Act and its implementing regulations, SBA is issuing this notice to announce the re-establishment of its Audit and Financial Management Advisory Committee. This advisory committee is being re-established to help the agency identify and address financial management topics determined by the Agency.

FOR FURTHER INFORMATION CONTACT: Questions about the Audit and Financial Management Advisory Committee may be directed to John Kushman, telephone (202) 205–6103, fax (202) 481–2671, email *john.kushman@sba.gov* or mail, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Pursuant to its authority in section 8(b)(13) of the Small Business Act, (15 U.S.C. 637(b)), SBA is re-establishing the Audit and Financial Management Advisory Committee (AFMAC or the Committee). This discretionary committee is being re-established in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

The AFMAC provides advice and recommendations to SBA on government accounting and performance issues impacting the Agency. The AFMAC's scope of activities includes providing advice as to industry best practices and methods of improving results relating to SBA's financial reporting and auditing processes, financial systems, internal controls, performance measures and recommendations on how to better comply with laws and regulations governing federal financial management.

The Committee has a total of three (3) members, including one Chairperson selected by the SBA Administrator. Members serve as representatives of the financial management community and may consist of financial managers, auditors, chief financial officers or financial management and accounting trade organizations.

Dated: January 31, 2014.

Diana Doukas,

SBA Committee Management Officer.

[FR Doc. 2014–02709 Filed 2–7–14; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes one new information collection, and revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than April 11, 2014. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Promoting Readiness of Minors in SSI (PROMISE) Evaluation—0960–NEW.

Background

The Promoting Readiness of Minors in SSI (PROMISE) demonstration pursues positive outcomes for children with disabilities who receive Supplemental Security Income (SSI) and their families by reducing dependency on SSI. The Department of Education (ED) awarded six cooperative agreements to states to improve the provision and coordination of services and support for children with disabilities who receive SSI and their families to achieve improved education and employment outcomes. ED awarded PROMISE funds to five single-state projects, and to one six-state consortium.[1] With support from the Department of Labor (DOL) and the Department of Health and Human Services (HHS), SSA will evaluate the six PROMISE projects. SSA contracted with Mathematica Policy Research to conduct the evaluation.

Under PROMISE, targeted outcomes for youth include an enhanced sense of self-determination; achievement of secondary and post-secondary educational credentials; an attainment of early work experiences culminating with competitive employment in an integrated setting; and long-term reduction in reliance on SSI. Outcomes of interest for families include heightened expectations for and support of the long-term self-sufficiency of their youth; parent or guardian attainment of education and training credentials; and increases in earnings and total income. To achieve these outcomes, we expect the PROMISE projects to make better use of existing resources by improving service coordination among multiple state and local agencies and programs.

ED, SSA, DOL, and HHS intend the PROMISE projects to address key limitations in the existing service system for youth with disabilities. By intervening early in the lives of these young people, at ages 14–16, the projects will engage the youth and their families well before critical decisions regarding the age 18 redetermination are upon them. We expect the required partnerships among the various state and Federal agencies that serve youth with disabilities to result in improved integration of services and fewer dropped handoffs as youth move from one agency to another. By requiring the programs to engage and serve families and provide youth with paid work experiences, the initiative is mandating the adoption of critical best practices in promoting the independence of youth with disabilities.

Project Description

SSA is requesting clearance for the collection of data needed to implement and evaluate PROMISE. The evaluation will provide empirical evidence on the impact of the intervention for youth and their families in several critical areas, including: (1) Improved educational attainment; (2) increased employment skills, experience, and earnings; and (3) long-term reduction in use of public benefits. We will base the PROMISE evaluation on a rigorous design that will entail the random assignment of approximately 2,000 youth in each of the six projects to treatment or control groups (12,000 total). Youth in the treatment groups will be eligible for enhanced services from the demonstration programs, whereas youth in the control groups will be eligible only for those services already available in their communities independent of the interventions.

The evaluation will assess the effect of PROMISE services on educational attainment, employment, earnings, and reduced receipt of disability payments. The three components of this evaluation include:

- *The process analysis,* which will document program models, assess the relationships among the partner organizations, document whether the programs are implemented as planned, identify features of the programs that may account for their impacts on youth and families, and identify lessons for future programs with similar objectives.
- *The impact analysis,* which will determine whether youth and families in the treatment groups receive more services than their counterparts in the control groups. It will also determine whether treatment group members have better results than control group members with respect to the targeted outcomes noted above.
- *The cost-benefit analysis,* which will assess whether the benefits of PROMISE, including increases in

[1] The six-state consortium project goes by the name Achieving Success by Promoting Readiness for Education and Employment (ASPIRE) rather than by PROMISE.

employment and reductions in benefit receipt, are large enough to justify its costs. We will conduct this assessment from a range of perspectives, including those of the participants, state and Federal governments, SSA, and society as a whole.

SSA planned several data collection efforts for the evaluation. These include: (1) follow-up interviews with youth and their parent or guardian 18 months and 5 years after enrollment; (2) phone and in-person interviews with local program administrators, program supervisors, and service delivery staff at two points in time over the course of the demonstration; (3) two rounds of focus groups with participating youth in the treatment group; (4) two rounds of focus groups with parents or guardians of participating youth; and (5) collection of administrative data.

At this time, SSA requests clearance only for the interviews we will conduct with program staff and the focus group discussions we will conduct with youth and parents or guardians. We will conduct these interviews and group discussions twice: once in 2014, and once in 2016. SSA will request clearance for the 18-month and 5-year survey interviews in a future submission. The respondents are PROMISE program staff, the youth participants in the PROMISE program, and the parents or guardians of the youth participants.

Type of Request: This is a new information collection.

2014 Interviews and Focus Group Discussions

Modality of completion	Number of responses	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Staff Interviews with Administrators or Directors	75	1	66	83
Staff Interviews with PROMISE Project Staff	145	1	66	160
Youth Focus Groups—Non-participants	320	1	5	27
Youth Focus Groups—Participants	80	1	100	133
Parents or Guardian Focus Groups—Non-participants	320	1	5	27
Parents or Guardian Focus Groups—Participants	80	1	100	133
Totals	1,020			563

2016 Interviews and Focus Group Discussions

Modality of completion	Number of responses	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Staff Interviews with Administrators or Directors	75	1	66	83
Staff Interviews with PROMISE Project Staff	145	1	66	160
Youth Focus Groups—Non-participants	320	1	5	27
Youth Focus Groups—Participants	80	1	100	133
Parents or Guardian Focus Groups—Non-participants	320	1	5	27
Parents or Guardian Focus Groups—Participants	80	1	100	133
Totals	1,020			563
Grand Total	2,040			1,126

2. Request for Social Security Earnings Information—20 CFR 404.810 and 401.100—0960–0525. The Social Security Act permits wage earners, or their authorized representative, to request Social Security earnings information from SSA using Form SSA–7050–F4. SSA uses the information to verify the requestor's right to access the information and to produce the earnings statement. The respondents are wage earners and their authorized representatives.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–7050–F4	66,800	1	11	12,247

3. Request for Medical Treatment in an SSA Employee Health Facility: Patient Self-Administered or Staff Administered Care—0960–0772. SSA operates onsite Employee Health Clinics (EHC) in eight different states. These clinics provide health care for all SSA employees including treatments of personal medical conditions when authorized through a physician. Form SSA–5072 is the employee's personal physician's order form. The information we collect on Form SSA–5072 gives the EHC nurses the guidance they need by law to perform certain medical procedures and to administer prescription medications such as allergy immunotherapy. In addition, the information allows the SSA Medical Officer to determine whether the treatment can be administered safely and appropriately in the SSA EHCs. Respondents are physicians of SSA

employees who need to have medical treatment in an SSA EHC.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–5072 Annually	25	1	25	5	2
SSA–5072 Bi-Annually	75	2	150	5	13
Totals	100		175		15

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than March 12, 2014. Individuals can obtain copies of the OMB clearance packages by writing to OR.Reports.Clearance@ssa.gov.

Petition to Obtain Approval of a Fee for Representing a Claimant Before the Social Security Administration—20 CFR 404.1720 and 404.1725; 20 CFR 416.1520 and 416.1525—0960–0104. SSA attorney and non-attorney claimant representatives use Form SSA–1560–U4 to petition SSA for authorization to charge and collect a fee. Claimants may also use the form to agree with or contest the requested fee amount or other information the representative provides on the form. SSA officials use the form to determine a reasonable fee amount representatives may charge for their services. The respondents are attorneys and non-attorneys who represent Social Security claimants and their claimants.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1560–U4	48,110	1	30	24,055

Dated: February 5, 2014.

Faye Lipsky,

Reports Clearance Director, Social Security Administration.

[FR Doc. 2014–02776 Filed 2–7–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2014–0008]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes the collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before April 11, 2014.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2014–0008 using any of the following methods:

Electronic submissions: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1-(202) 493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form for all comments received into any of our dockets by the name of the individual submitting the comments (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit http://DocketsInfo.dot.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Russell Pierce, Contracting Officer's Technical Representative, Office of Behavioral Safety Research (NTI–132), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W46–472, Washington, DC 20590. Dr. Pierce's phone number is (202) 366–5599 and his email address is russell.pierce@dot.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult

with members of the public and affected agencies concerning each proposed collection of information. NHTSA asks public comment on the following proposed collection of information:

Questionnaires for Traffic and Motor Vehicle Safety Research

Type of Request—New Information Collection.

OMB Clearance Number—None.

Requested Expiration Date of Approval—3 years from date of approval.

Summary of the Collection of Information—The National Highway Traffic Safety Administration (NHTSA) proposes to collect questionnaires from research participants and potential research participants. The information collected will be used to improve the quality of the questions that will be used in subsequent approved data collection efforts. Data collections may be collected from volunteers in-person, via US mail, via email, via telephone, or via a Web site.

Description of the Need for the Information and Proposed Use of the Information—

The National Highway Traffic Safety Administration (NHTSA) was authorized by the Highway Safety Act of 1966 to carry out a Congressional mandate to reduce the mounting number of deaths, injuries and economic losses resulting from motor vehicle crashes on our Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of motor vehicle standards and traffic safety programs.

NHTSA is requesting generic clearance to conduct information collections in the form of questionnaires for the purposes of improving the integrity, quality, and utility of other approved data collection efforts. This clearance will enable NHTSA to undergo the type of iterative development process wherein the practical, conceptual, and mathematical properties of questions are evaluated; this approach is standard in research of the type NHTSA conducts. This will also serve to allow NHTSA to better serve the purposes set forth in 44 U.S.C. 3501 by producing a higher quality research product and avoiding any additional paperwork burden that may result from questions that fail to have suitable practical, conceptual, or mathematical properties.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)— Volunteers will be recruited from other approved NHTSA data collection efforts, NHTSA's traffic safety partners, or individuals recruited via advertisement based on questionnaire criteria. NHTSA anticipates needing approximately 2,000 participants per year. NHTSA anticipates that any volunteers recruited will only be contacted once in any given year.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information— Recruitment, scheduling, and the completion of questionnaires are estimated to require no more than 30 minutes per individual. Therefore, the total estimated annual reporting burden is 1,000 hours.

Public Comments Invited: Under OMB's regulations (at 5 CFR 1320.8(d)), you are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Issued on February 5, 2014.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2014–02808 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0019]

Technical Report Evaluating Curtain and Side Air Bags

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Request for comments on technical report.

SUMMARY: This notice announces NHTSA's publication of a technical report evaluating the fatality-reducing effectiveness of curtain and side air bags in the front seats of passenger cars and LTVs. The report's title is: *Updated Estimates of Fatality Reduction by Curtain and Side Air Bags in Side Impacts and Preliminary Analyses of Rollover Curtains.*

DATES: Comments must be received no later than June 10, 2014.

ADDRESS:

Report: The technical report is available on the Internet for viewing in PDF format at *http://www-nrd.nhtsa.dot.gov/Pubs/811882.pdf.* You may obtain a copy of the report free of charge by sending a self-addressed mailing label to Charles J. Kahane (NVS–431), National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590.

Comments: You may submit comments [identified by Docket Number NHTSA–2014–0019] by any of the following methods:

- Internet: To submit comments electronically, go to the U.S. Government regulations Web site at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Fax: Written comments may be faxed to 202–493–2251.
- Mail: Send comments to Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- Hand Delivery: If you plan to submit written comments by hand or courier, please do so at 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except federal holidays.
- You may call Docket Management at 1–800–647–5527.

Instructions: For detailed instructions on submitting comments and additional information see the Comments heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Charles J. Kahane, Chief, Evaluation Division, NVS–431, National Center for Statistics and Analysis, National Highway Traffic Safety Administration, Room W53–312, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: 202–366–2560. Email: *chuck.kahane@dot.gov.*

SUPPLEMENTARY INFORMATION: Curtain and side air bags are designed to protect occupants in near-side impacts, those to the sides of vehicles adjacent to where

the occupants are seated. Four major types of curtain and/or side air bags have been available in the United States since 1996. However, by model year 2011, 85 percent of new cars and LTVs (light trucks and vans) were equipped with curtains plus torso bags for drivers and right-front passengers. Curtains that deploy in rollover crashes began to appear in 2002; by 2011 about 45 percent of new cars and LTVs were equipped with such curtains.

Logistic regression analyses of FARS data through calendar year 2011 show statistically significant fatality reductions for all four types of curtain and side air bags in near-side impacts for drivers and right-front passengers of cars and LTVs: curtains plus torso bags, 31.3 percent (confidence bounds, 25.0 to 37.1%); combination head/torso bags, 24.8 percent (confidence bounds, 17.7 to 31.2%); curtains only, 16.4 percent (confidence bounds, 3.0 to 28.0%); and torso bags only, 7.8 percent (confidence bounds, 0.4 to 14.7%).

Corresponding analyses of far-side impacts do not show corresponding, large benefits for curtain or side air bags. Curtains that deploy in rollover crashes show a statistically significant effect in first-event rollovers: The estimated fatality reduction is 41.3 percent (confidence bounds, 22.5 to 55.5%). Analyses should be repeated in about 3 or 4 years, when there will be considerably more data available.

In 2007, NHTSA upgraded FMVSS No. 214, "Side impact protection" by adding a crash test of a 20 mph side impact with a pole, at a 75-degree angle (72 FR 51908). The agency anticipated that head-protection air bags such as curtains or combination bags would generally be installed to meet the new requirement. In 2011, NHTSA issued FMVSS No. 226, "Ejection mitigation" (76 FR 3212), anticipating that containment of the occupant would be achieved in many vehicles by curtains designed to deploy in rollovers.

The technical report updates NHTSA's preliminary evaluation of curtain and side air bags, issued in 2007 (72 FR 12857).

Comments

How can I influence NHTSA's thinking on this subject?

NHTSA welcomes public review of the technical report. NHTSA will submit to the Docket a response to the comments and, if appropriate, will supplement or revise the report.

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA–2014–0019) in your comments.

Your primary comments must not be more than 15 pages long (49 CFR 553.21). However, you may attach additional documents to your primary comments. There is no limit on the length of the attachments.

Please submit one copy of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *http://www.whitehouse.gov/omb/fedreg_reproducible.* DOT's guidelines may be accessed at *http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/index.html.*

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://www.regulations.gov.*

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail. You may also periodically access *http://www.regulations.gov* and enter the number for this docket (NHTSA–2014–0019) to see if your comments are on line.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR Part 512.)

Will the agency consider late comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

(2) FDMS provides two basic methods of searching to retrieve dockets and docket materials that are available in the system: (a) "Quick Search" to search using a full-text search engine, or (b) "Advanced Search," which displays various indexed fields such as the docket name, docket identification number, phase of the action, initiating office, date of issuance, document title, document identification number, type of document, **Federal Register** reference, CFR citation, etc. Each data field in the advanced search may be searched independently or in combination with other fields, as desired. Each search yields a simultaneous display of all available information found in FDMS that is relevant to the requested subject or topic.

(3) You may download the comments. However, since the comments are imaged documents, instead of word processing documents, the "pdf" versions of the documents are word searchable.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you

periodically check the Docket for new material.

Authority: 49 U.S.C. 30111, 30181–83 delegation of authority at 49 CFR 1.95 and 501.8.

Issued in Washington, DC, on February 4, 2014.

Terry Shelton,

Associate Administrator for the National Center for Statistics and Analysis.

[FR Doc. 2014–02713 Filed 2–7–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35724 (Sub-No. 1)]

California High-Speed Rail Authority—Construction Exemption—In Fresno, Kings, Tulare, and Kern Counties, Cal.

By petition filed on September 26, 2013, California High-Speed Rail Authority (Authority), a state agency formed in 1996, seeks an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 for authority to construct an approximately 114-mile high-speed passenger rail line between Fresno and Bakersfield, Cal. (the Line).[1]

In a decision served December 20, 2013 (December 2013 decision), the Authority was required to notify all parties of record in the main docket (that is, Docket No. FD 35724, pertaining to construction of the Merced-to-Fresno HST segment) of its proposed transaction in this sub-docket (construction of the Fresno-to-Bakersfield HST segment) by providing them with a copy of the September 26, 2013 petition for exemption filed in this sub-docket, Docket No. 35724 (Sub-No. 1), as well as a copy of the Board's December 2013 decision, by January 3, 2014, and to certify contemporaneously to the Board that it had done so. Those parties, and any other interested persons who wished to participate in this sub-docket as a party of record, had until January 21, 2013, to notify the Board of their intent to participate in this sub-docket as a party of record. The December 2013 decision also extended the deadline for comments on the transportation merits of the proposed Fresno-to-Bakersfield Line construction to February 14, 2014.

On January 2, 2014, the Authority submitted a certificate of service indicating that it had served copies of its petition for exemption filed in this proceeding and the Board's December 2013 decision on "all parties of record in the main docket," but listing the names of the parties of record in this sub-docket, rather than the main docket.

On January 22, 2014, Citizens for California High-Speed Rail Accountability (CCHSRA) and Kings County Water District submitted separate comments, stating that the Authority had failed to comply with the Board's order in that the Authority served the incorrect petition on the incorrect service list.[2]

Thereafter, the Authority corrected its error by submitting a revised certificate of service indicating that on January 24, 2014, the Authority served its September 26, 2013 petition and the December 2013 decision on all parties of record in the main docket.

Because of the delay in providing notice to parties of the proposed transaction, the deadline for interested persons to notify the Board of their intent to participate in this sub-docket as a party of record will be extended to February 11, 2014. The deadline for comments on the transportation merits of the proposed Fresno-to-Bakersfield Line construction will be extended to March 7, 2014.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. Any person who wishes to participate in this proceeding as a party of record must file with the Board a notice of intent to participate by February 11, 2014.

2. Replies to the petition for exemption are due by March 7, 2014.

3. This decision will be published in the **Federal Register**.

4. This decision is effective on its service date.

Decided: February 3, 2014.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2014–02689 Filed 2–7–14; 8:45 am]

BILLING CODE 4915–01–P

[1] By decision served June 13, 2013, in *California High-Speed Rail Authority—Construction Exemption—in Merced, Madera, & Fresno Counties, Cal.*, FD 35724 (the main docket), the Board granted an exemption for the Authority to construct the first 65-mile segment of the planned California High-Speed Train System (HST System), between Merced and Fresno, California. The Line is the second segment of the proposed HST System.

[2] CCHSRA also re-raises arguments previously asserted in this case that (1) the deadline for comments on the transportation merits of the proposed transaction should be postponed until after the Final EIR/EIS is adopted, and (2) the Board must require the Authority to provide actual notice of this proceeding by mail to all affected landowners. These arguments were addressed in the Board's December 2013 decision, and CCHSRA has not demonstrated any material error or changed circumstances, or provided any new evidence, warranting a different conclusion on those issues.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the election to expense certain depreciable business assets.

DATES: Written comments should be received on or before April 11, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to R. Joseph Durbala, (202) 317–5746, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224 or through the Internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Election to Expense Certain Depreciable Business Assets.

OMB Number: 1545–1201.

Regulation Project Number: TD 9209(final).

Abstract: The regulations provide rules on the election described in Internal Revenue Code section 179(b)(4); the apportionment of the dollar limitation among component members of a controlled group; and the proper order for deducting the carryover of disallowed deduction. The recordkeeping and reporting requirements are necessary to monitor compliance with the section 179 rules.

Current Actions: There is no change to these existing regulations. However, we

are updating the reported OMB burden estimates to be consistent with what was provided in the regulations.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, farms, and business or other for-profit organizations.

Estimated Number of Respondents: 4,025,000.

Estimated Time Per Respondent: 45 min.

Estimated Total Annual Burden Hours: 3,015,000.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 28, 2014.

Christie Preston,

Supervisory Tax Analyst, Internal Revenue Service.

[FR Doc. 2014–02847 Filed 2–7–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8944 and Form 8948

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8944, Preparer Hardship Waiver Request, and Form 8948, Preparer Explanation for Not Filing Electronically.

DATES: Written comments should be received on or before April 11, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Joseph Durbala at (202) 317–5746, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 8944, Preparer Hardship Waiver Request,

Title: Form 8948, Preparer Explanation for Not Filing Electronically.

OMB Number: 1545–2200.

Abstract Form 8944: A tax preparer uses Form 8944 to request a waiver from the requirement to file tax returns on magnetic media when the filing of tax returns on magnetic media would cause a hardship.

Abstract, Form 8948: A specified tax return preparer uses Form 8948 to explain which exception applies when a covered return is prepared and filed on paper.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 8,910,000.

Estimated Total Annual Burden Hours: 18,270,900

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 3, 2014.

Christie Preston,

IRS, Supervisory Tax Analyst.

[FR Doc. 2014–02840 Filed 2–7–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for 637 Registration Program

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this

opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the 637 Registration Program.

DATES: Written comments should be received on or before April 11, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on the burden related to the 637 registration program should be directed to R. Joseph Durbala, (202)–317–5746, at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: 637 Registration Program.

OMB Number: 1545–1835.

Form Number: 637

Abstract: The authority for the requirement for registration is found in Internal Revenue Code sections 4101 (Fuel Taxes), 4222 (Retailers and Manufacturers Excise Taxes), 4682 (Ozone-depleting Chemicals Tax), and the regulations. Form 637, Application for Registration (For Certain Excise Tax Activities) is used to apply for excise tax registration for activities under sections 4101, 4222, and 4682. Common activities for which persons are registered include that of a refiner, terminal operator, position holder, throughputter, ultimate vendor, first retail seller of certain heavy vehicles, manufacturer of sport fishing equipment, and to file a claim. The information will be used to make an informed decision on whether the applicant/registrant qualifies for registration.

Current Actions: There are no changes being made to the burden associated with the collection tools at this time. However, this request will be used to combine the associated burden of 1545–0014 into this approval number.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 4,840.

Estimated Average Time per Respondent: 6 hours, 30 minutes.

Estimated Total Annual Burden Hours: 30,499.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 4, 2014.

Christie Preston,

Supervisory Tax Analyst, Internal Revenue Service.

[FR Doc. 2014–02844 Filed 2–7–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0605]

Proposed Information Collection (Removal of Requirement to File Direct-Pay Fee Agreements with the Office of the General Counsel)

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of the General Counsel (OGC), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the modification of a collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each modification of a collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the removal of the requirement that direct-pay fee agreements be filed with both the agency of original jurisdiction (AOJ) and OGC. Direct-pay fee agreements would only be filed with the AOJ.

DATES: Comments must be received on or before April 11, 2014.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at www.Regulations.gov or to Dana Raffaelli (022O), Office of the General Counsel, U.S. Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420. Please refer to "OMB Control No. 2900–0605" in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Dana Raffaelli at (202) 461–7699 or FAX (202) 273–6404. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

Title: Filing of Representatives' Fee Agreements.

OMB Control Number: 2900–0605

Type of Review: Revision of a currently approved collection.

Abstracts:

a. *Summary of collection of information:* Accredited agents and attorneys are required to file with the Secretary of Veterans Affairs agreements for the payment of fees charged for representing claimants before VA. The Secretary is authorized to review these agreements either on his or her own motion or upon the request of the claimant who is a party to the agreement. 38 U.S.C. 5904(c). The purpose of the review is to determine whether the fees charged are excessive or unreasonable. Id. VA regulations delegate the authority to receive and review fee agreements to OGC. 38 CFR 14.636. Subject to certain limitations, attorneys and agents may enter into agreements with claimants that direct VA to withhold representation fees from any past-due benefits VA awards to the claimant and pay the fee directly to the agent or attorney. 38 U.S.C. 5904(d). To process direct payments, VA requires filing a copy of a fee agreement with the local VA regional office where award payments are processed, i.e., the AOJ. 38 CFR 14.636(h)(4). VA is amending § 14.636(g)(3) and (h)(4) to remove the requirement that an agent or attorney file a direct-pay fee agreement with both OGC and the AOJ. The intended effect of this amendment is to require that

direct-pay fee agreements be submitted only to the AOJ, thereby eliminating duplicate filings by agents and attorneys. In cases where OGC needs to review a direct-pay fee agreement, it can obtain a copy of the agreement from the AOJ.

b. *Description of need for information and proposed use of information:* The information is used by VA in reviewing fee agreements between VA claimants and their representatives to determine whether they are in compliance with the law governing representation and fees, and by VA regional offices in processing direct-fee payment agreements.

c. *Description of likely respondents:* VA-accredited agents and attorneys.

d. *Estimated number of respondents:* There are currently about 12,600 VA-accredited agents and attorneys. Approximately 1,200 agents and attorneys have filed fee agreements (direct and non-direct) with OGC over the past five years.

e. *Estimated frequency of responses:* OGC receives approximately 11,700 direct-pay fee agreements per year. Therefore, on average, each respondent files approximately 9–10 direct-pay fee agreements with OGC per year, which will be eliminated with this rulemaking.

f. *Estimated average burden per response:* VA estimates an average hour burden reduction of 10 minutes per response for the removal of the duplicate filing of a direct-pay fee agreement with OGC.

g. *Estimated total annual reporting and recordkeeping burden:* VA estimates a total annual burden reduction of 1950 hours for all respondents for the removal of the duplicate filing of a direct-pay fee agreement with OGC.

Dated: February 5, 2014.

By direction of the Secretary:

Crystal Rennie,

VA Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2014–02798 Filed 2–7–14; 8:45 am]

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Part II

Department of Energy

10 CFR Part 431
Energy Conservation Program: Energy Conservation Standards for Metal Halide Lamp Fixtures; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket Number EERE–2009–BT–STD–0018]

RIN 1904–AC00

Energy Conservation Program: Energy Conservation Standards for Metal Halide Lamp Fixtures

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The Energy Policy and Conservation Act of 1975 (EPCA), as amended, prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including metal halide lamp fixtures (MHLFs). EPCA also requires the U.S. Department of Energy (DOE) to determine whether more-stringent standards would be technologically feasible and economically justified, and would save a significant amount of energy. In this final rule, DOE is adopting more-stringent energy conservation standards for MHLFs. It has determined that the new and amended energy conservation standards for this equipment would result in significant conservation of energy, and are technologically feasible and economically justified.

DATES: The effective date of this rule is April 11, 2014. Compliance with the new and amended standards established for MHLFs in today's final rule is required by February 10, 2017.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register on April 11, 2014.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at regulations.gov. All documents in the docket are listed in the regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

A link to the docket Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/16*. The regulations.gov Web page will contain simple instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: *metal_halide_lamp_fixtures@ee.doe.gov*.

Mr. Ari Altman, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–6307. Email: *ari.altman@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Summary of the Final Rule and Its Benefits

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles.[2] Pursuant to EPCA, any new or amended energy conservation standard that DOE prescribes for certain equipment, such as metal halide lamp fixtures (MHLFs or "fixtures" [3]), shall be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) In accordance with these and other statutory provisions discussed in this notice, DOE is adopting new and amended energy conservation standards for MHLFs. The new and amended standards, which are the minimum allowable ballast efficiencies [4] based on fixture location, ballast type, and rated lamp wattage, are shown in Table I.1. These new and amended standards apply to all equipment listed in Table I.1 and manufactured in, or imported into, the United States on or after the compliance date in the **DATES** section of this notice (additionally, see section II.B.3 of this notice for more information on the compliance date determination).

TABLE I.1—ENERGY CONSERVATION STANDARDS FOR MHLFS

Designed to be operated with lamps of the following rated lamp wattage	Indoor/outdoor	Test input voltage †	Minimum standard equation ‡ %
≥50 W and ≤100 W	Indoor	480 V	(1/(1+1.24×P^(−0.351))) − 0.0200.
≥50 W and ≤100 W	Indoor	All others	1/(1+1.24×P^(−0.351)).
≥50 W and ≤100 W	Outdoor	480 V	(1/(1+1.24×P^(−0.351))) − 0.0200.
≥50 W and ≤100 W	Outdoor	All others	1/(1+1.24×P^(−0.351)).
>100 W and <150 W*	Indoor	480 V	(1/(1+1.24×P^(−0.351))) − 0.0200.
>100 W and <150 W*	Indoor	All others	1/(1+1.24×P^(−0.351)).
>100 W and <150 W*	Outdoor	480 V	(1/(1+1.24×P^(−0.351))) − 0.0200.
>100 W and <150 W*	Outdoor	All others	1/(1+1.24×P^(−0.351)).
≥150 W** and ≤250 W	Indoor	480 V	0.880.
≥150 W** and ≤250 W	Indoor	All others	For ≥150 W and ≤200 W: 0.880. For >200 W and ≤250 W: 1/(1+0.876×P^(−0.351)).
≥150 W** and ≤250 W	Outdoor	480 V	0.880.

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (Dec. 18, 2012).

[3] The scope of this rulemaking encompasses entire MHLFs, including the metal halide lamps and metal halide ballasts the fixtures contain. Therefore, the ratings of individual components are often discussed at a system level. For example, when referring to the rated wattages or available input voltages of the lamps and ballasts a fixture is designed to operate with, this final rule frequently uses shorthand such as "100 W ballast" for a ballast operating a lamp rated at 100 watts or "480 V fixture" for a fixture housing a ballast with a dedicated input voltage of 480 volts.

[4] DOE is proposing to continue using a ballast efficiency metric for regulation of MHLFs, rather than a system or other approach. See section 0 for further discussion.

TABLE I.1—ENERGY CONSERVATION STANDARDS FOR MHLFS—Continued

Designed to be operated with lamps of the following rated lamp wattage	Indoor/outdoor	Test input voltage †	Minimum standard equation ‡ %
≥150 W** and ≤250 W	Outdoor	All others	For ≥150 W and ≤200 W: 0.88. For >200 W and ≤250 W: 1/(1+0.876×P^(−0.351)).
>250 W and ≤500 W	Indoor	480 V	For >250 W and <265 W: 0.880. For ≥265 W and ≤500 W: (1/(1+0.876×P^(−0.351))) − 0.0100.
>250 W and ≤500 W	Indoor	All others	1/(1+0.876×P^(−0.351)).
>250 W and ≤500 W	Outdoor	480 V	For >250 W and <265 W: 0.880. For ≥265 W and ≤500 W: (1/(1+0.876×P^(−0.351))) − 0.0100.
>250 W and ≤500 W	Outdoor	All others	1/(1+0.876×P^(−0.351)).
>500 W and ≤1000 W	Indoor	480 V	>500 W and ≤750 W: 0.900. >750 W and ≤1000 W: 0.000104×P + 0.822. For >500 W and ≤1000 W: may not utilize a probe-start ballast.
>500 W and ≤1000 W	Indoor	All others	For >500 W and ≤750 W: 0.910. For >750 W and ≤1000 W: 0.000104×P+0.832. For >500 W and ≤1000 W: may not utilize a probe-start ballast.
>500 W and ≤1000 W	Outdoor	480 V	>500 W and ≤750 W: 0.900. >750 W and ≤1000 W: 0.000104×P + 0.822. For >500 W and ≤1000 W: may not utilize a probe-start ballast.
>500 W and ≤1000 W	Outdoor	All others	For >500 W and ≤750 W: 0.910. For >750 W and ≤1000 W: 0.000104×P+0.832. For >500 W and ≤1000 W: may not utilize a probe-start ballast.

* Includes 150 W fixtures specified in paragraph (b)(3) of this section, which are fixtures rated only for 150 watt lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W fixtures specified in paragraph (b)(3) of this section, which are fixtures rated only for 150 watt lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† Tested input voltage is specified in 10 CFR 431.324.

‡ P is defined as the rated wattage of the lamp the fixture is designed to operate.

A. Benefits and Costs to Customers

Table I.2 presents DOE's evaluation of the economic impacts of today's standards on customers of MHLFs, as measured by the average life-cycle cost (LCC) savings and the median payback period. The average LCC savings are positive for a majority of users for all equipment classes.

TABLE I.2—IMPACTS OF TODAY'S STANDARDS ON CUSTOMERS OF MHLFS *

Representative equipment class	Representative wattage	Average LCC savings *2012$*	Median payback period *years*
≥50 W and ≤100 W (indoor, magnetic baseline)	70 W	27.00	4.5
≥50 W and ≤100 W (outdoor, magnetic baseline)	70 W	34.88	4.5
>100 W and <150 W** (indoor)	150 W	24.63	7.3
>100 W and <150 W** (outdoor)	150 W	30.70	8.1
≥150 W† and ≤250 W (indoor)	250 W	4.51	14.2
≥150 W† and ≤250 W (outdoor)	250 W	6.74	17.4
>250 W and ≤500 W (indoor)	400 W	7.95	15.0
>250 W and ≤500 W (outdoor)	400 W	13.15	18.4
>500 W and ≤1000 W (indoor)	1000 W	1221.54	0.8
>500 W and ≤1000 W (outdoor)	1000 W	1631.94	0.8

* On average, indoor and outdoor fixtures have 20- and 25-year lifetimes, respectively.

** Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the National Electrical Code 2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2001.

† Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the National Electrical Code 2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2001.

B. Impact on Manufacturers

The industry net present value (INPV) is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2014 to 2046). Using a real discount rate of 8.9 percent, DOE estimates that the base case INPV for manufacturers of MH ballasts ranges from $67 million in the low-shipment scenario to $74 million in the high-shipment scenario in 2012$. Under today's standards, DOE expects that ballast manufacturers may lose up to 26.7 percent of their INPV, which is approximately $17.9 million, in the low-shipment, preservation of operating profit markup scenario.

For MHLF, using a real discount rate of 9.5 percent, DOE estimates that the base case INPV for manufacturers of MHLFs ranges from $346 million in the low-shipment

scenario to $379 million in the high-shipment scenario in 2012$. Under today's standards, DOE expects that MHLF manufacturers may lose up to 1.0 percent of their INPV, which is approximately $3.6 million, in the low-shipment, preservation of operating profit markup scenario.

When adding these two MH industries together (MHLF and MH ballast), DOE estimates that the combined base case INPV for manufacturers of MHLFs and MH ballasts ranges from $413 million in the low-shipment scenario to $453 million in the high-shipment scenario in 2012$. Under today's standards, DOE expects that all MH manufacturers (MHLF and MH ballast manufacturers) may lose up to 5.2 percent of their INPV, which is approximately $21.5 million, in the low-shipment, preservation of operating profit markup scenario.

Additionally, based on DOE's interviews with manufacturers of MHLFs and ballasts, DOE does not expect any plant closings or significant loss of employment.

C. National Benefits[5]

DOE's analyses indicate that today's standards would save a significant amount of energy. The lifetime savings for MHLFs purchased in the 30-year period that begins in the year of compliance with new and amended standards (2017–2046) amount to 0.39–0.49 quads.

The cumulative net present value (NPV) of total customer costs and savings of today's standards for MHLFs ranges from $0.29 billion (at a 7-percent discount rate, low shipments scenario) to $1.1 billion (at a 3-percent discount rate, high shipments scenario). This NPV expresses the estimated total value of future operating cost savings minus the estimated increased equipment costs for equipment purchased in 2017–2046.

In addition, today's standards would have significant environmental benefits. The energy savings would result in cumulative greenhouse gas emission reductions of approximately 22.5–27.8 million metric tons (Mt)[6] of carbon dioxide (CO_2), 105.9–132.4 thousand tons of methane, 0.5–0.6 thousand tons of nitrous oxide (N_2O), 37.5–47.2 thousand tons of sulfur dioxide (SO_2), 28.2–35.0 tons of nitrogen oxides (NO_X) and 0.05–0.06 tons of mercury (Hg).[3] Through 2030, the estimated energy savings would result in cumulative emissions reductions of 6.3–6.8 Mt of CO_2.

The value of the CO_2 reductions is calculated using a range of values per metric ton of CO_2 (otherwise known as the Social Cost of Carbon or SCC) developed by a recent interagency process.[7] The derivation of the SCC values is discussed in section V.M. Using discount rates appropriate for each set of SCC values, DOE estimates that the net present monetary value of the CO_2 emissions reductions is between $0.15 billion and $2.55 billion. DOE also estimates that the net present monetary value of the NO_X emissions reductions is $17.34 million at a 7-percent discount rate, and $44.20 million at a 3-percent discount rate.[8]

Table I.3 summarizes the national economic costs and benefits expected to result from today's standards for MHLFs.

TABLE I.3—SUMMARY OF NATIONAL ECONOMIC BENEFITS AND COSTS OF MHLF ENERGY CONSERVATION STANDARDS *

Category	Present value million 2012$	Discount rate (%)
Benefits		
Operating Cost Savings	754	7
	1,636	3
CO_2 Reduction Monetized Value ($11.8/t case) **	146	5
CO_2 Reduction Monetized Value ($39.7/t case) **	682	3
CO_2 Reduction Monetized Value ($61.2/t case) **	1,088	2.5
CO_2 Reduction Monetized Value ($117/t case) **	2,106	3
NO_X Reduction Monetized Value (at $2639/ton) **	17	7
	37	3
Total Benefits †	1,453	7
	2,355	3
Costs		
Incremental Installed Costs	465	7
	721	3
Net Benefits		
Including CO_2 and NO_X † Reduction Monetized Value	988	7
	1,634	3

* This table presents the primary (low shipments scenario) estimate of costs and benefits associated with fixtures shipped in 2017–2046. These results include benefits to customers which accrue after 2047 from the equipment purchased in 2017–2046. The results account for the incremental variable and fixed costs incurred by manufacturers due to the standard, some of which may be incurred in preparation for the rule.

** The CO_2 values represent global monetized values of the SCC, in 2012$, in 2015 under several scenarios of the updated SCC values. The first three cases use the averages of SCC distributions calculated using 5%, 3%, and 2.5% discount rates, respectively. The fourth case represents the 95th percentile of the SCC distribution calculated using a 3% discount rate. The SCC time series used by DOE incorporate an escalation factor. The value for NO_X is the average of the low and high values used in DOE's analysis.

† Total Benefits for both the 3% and 7% cases are derived using the series corresponding to average SCC with a 3-percent discount rate.

The benefits and costs of today's standards, for equipment sold in 2017–2046, can also be expressed in terms of annualized values. The annualized monetary values are the sum of (1) the annualized national economic value of the benefits from operating the equipment (consisting primarily of operating cost savings from using less energy, minus increases in equipment purchase and

[5] All monetary values in this section are expressed in 2012 dollars and are discounted to 2013. Value ranges correspond with estimates for the low and high shipment scenarios.

[6] A metric ton is equivalent to 1.1 short tons. Results for NO_X and Hg are presented in short tons.

[3] DOE calculated emissions reductions relative to the *Annual Energy Outlook* (*AEO*) 2013 Reference case, which generally represents current legislation and environmental regulations for which implementing regulations were available as of December 31, 2012.

[7] Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. Interagency Working Group on Social Cost of Carbon, United States Government. May 2013 (Revised November 2013). *www.whitehouse.gov/sites/default/files/omb/assets/inforeg/technical-update-social-cost-of-carbon-for-regulator-impact-analysis.pdf.*

[8] DOE is currently investigating valuation of avoided Hg and SO_2 emissions.

installation costs, which is another way of representing customer NPV), plus (2) the annualized monetary value of the benefits of emission reductions, including CO_2 emission reductions.[9]

Although adding the value of customer savings to the values of emission reductions provides a valuable perspective, two issues should be considered. First, the national operating cost savings are domestic U.S. customer monetary savings that occur as a result of market transactions, while the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and CO_2 savings are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of MHLFs shipped in 2017–2046. The SCC values, on the other hand, reflect the present value of all future climate-related impacts resulting from the emission of one metric ton of carbon dioxide in each year. These impacts continue well beyond 2100.

Estimates of annualized benefits and costs of today's standards are shown in Table I.4. The results under the primary estimate are as follows. Using a 7-percent discount rate for benefits and costs other than CO_2 reduction, for which DOE used a 3-percent discount rate along with the average SCC series that uses a 3-percent discount rate, the cost of the standards in today's rule is $46 million per year in increased equipment costs, while the benefits are $74 million per year in reduced equipment operating costs, $38 million in CO_2 reductions, and $1.71 million in reduced NO_X emissions. In this case, the net benefit amounts to $68 million per year. Using a 3-percent discount rate for all benefits and costs and the average SCC series, the cost of the standards in today's rule is $40 million per year in increased equipment costs, while the benefits are $91 million per year in reduced operating costs, $38 million in CO_2 reductions, and $2.07 million in reduced NO_X emissions. In this case, the net benefit amounts to $91 million per year.

TABLE I.4—ANNUALIZED BENEFITS AND COSTS OF NEW AND AMENDED STANDARDS FOR MHLFS

	Discount rate	Primary (low) net benefits estimate* *Million 2012$/year*	High net benefits estimate* *Million 2012$/year*
Benefits			
Operating Cost Savings	7%	74	92
	3%	91	119
CO_2 Reduction at ($11.8 case)**	5%	11	13
CO_2 Reduction at ($39.7/t case)**	3%	38	46
CO_2 Reduction at ($61.2/t case)**	2.5%	56	68
CO_2 Reduction at ($117.0/t case)**	3%	117	142
NO_X Reduction at ($2639/ton)**	7%	1.71	1.95
	3%	2.07	2.46
Total Benefits†	7% plus CO_2 range	87 to 194	107 to 236
	7%	114	140
	3%	131	168
	3% plus CO_2 range	104 to 211	135 to 264
Costs			
Incremental Product Costs	7%	46	52
	3%	40	48
Net Benefits			
Total†	7% plus CO_2 range	41 to 148	54 to 184
	7%	68	87
	3%	91	120
	3% plus CO_2 range	64 to 171	87 to 216

*This table presents the annualized costs and benefits associated with fixtures shipped in 2017–2046. These results include benefits to consumers which accrue after 2046 from the fixtures purchased from 2017–2046. The results account for the incremental variable and fixed costs incurred by manufacturers due to the standard, some of which may be incurred in preparation for the rule. The Primary (Low) and High Benefits Estimates utilize projections of energy prices from the *AEO2013* Reference case and High Estimate, respectively. The Primary (Low) and High Benefits Estimates are also based on projected fixture shipments in the Low Shipments, Roll-up and High Shipments, Roll-up scenarios, respectively. In addition, the Primary (Low) estimate uses incremental equipment costs that assume fixed equipment prices throughout the analysis period. The High estimate uses incremental equipment costs that reflect a declining trend for equipment prices, using *AEO* price trends (deflators). The methods used to derive projected price trends are explained in section V.F.1.

**The CO_2 values represent global monetized values of the SCC, in 2012$, in 2015 under several scenarios of the updated SCC values. The first three cases use the averages of SCC distributions calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth case represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate. The SCC time series used by DOE incorporate an escalation factor. The value for NO_X is the average of the low and high values used in DOE's analysis.

† Total Benefits for both the 3-percent and 7-percent cases are derived using the series corresponding to average SCC with 3-percent discount rate. In the rows labeled "7% plus CO_2 range" and "3% plus CO_2 range," the operating cost and NO_X benefits are calculated using the labeled discount rate, and those values are added to the full range of CO_2 values.

D. Conclusion

Based on the analyses culminating in this final rule, DOE found the benefits to the nation of the standards (energy savings, customer LCC savings, positive NPV of customer benefit, and emission reductions) outweigh the burdens (loss of INPV and LCC increases for some users of this equipment). DOE has concluded that the standards in

[9] DOE used a two-step calculation process to convert the time-series of costs and benefits into annualized values. First, DOE calculated a present value in 2013, the year used for discounting the NPV of total customer costs and savings, for the time-series of costs and benefits using discount rates of 3 and 7 percent for all costs and benefits except for the value of CO_2 reductions. For the latter, DOE used a range of discount rates, as shown in Table I.3. From the present value, DOE then calculated the fixed annual payment over a 30-year period (2017 through 2046) that yields the same present value. The fixed annual payment is the annualized value. Although DOE calculated annualized values, this does not imply that the time-series of cost and benefits from which the annualized values were determined is a steady stream of payments.

today's final rule represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in significant conservation of energy.

II. Introduction

The following section briefly discusses the statutory authority underlying today's final rule, as well as some of the relevant historical background related to the establishment of standards for MHLFs.

A. Authority

Title III, Part B [10] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as "covered equipment"),[11] which includes the types of MHLFs that are the subject of this rulemaking. (42 U.S.C. 6292(a)(19)) EPCA, as amended by the Energy Independence and Security Act of 2007 (EISA 2007) prescribes energy conservation standards for this equipment (42 U.S.C. 6295(hh)(1)), and directs DOE to conduct a rulemaking to determine whether to amend these standards. (42 U.S.C. 6295(hh)(2)(A)) DOE notes that under 42 U.S.C. 6295(hh)(3)(A), the agency must conduct a second review of energy conservation standards for MHLFs and publish a final rule no later than January 1, 2019.

Pursuant to EPCA, DOE's energy conservation program for covered equipment consists essentially of four parts: (1) Testing; (2) labeling; (3) the establishment of federal energy conservation standards; and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling, and DOE implements the remainder of the program. Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of covered equipment. (42 U.S.C. 6293) Manufacturers of covered equipment must use the prescribed DOE test procedure as the basis for certifying to DOE that their equipment complies with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of that equipment. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the equipment complies with standards adopted pursuant to EPCA. *Id.* DOE test procedures for MHLFs currently appear at title 10 of the Code of Federal Regulations (CFR) section 431.324.

DOE must follow specific statutory criteria for prescribing new or amended standards for covered equipment. As indicated above, any new or amended standard for covered equipment must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)) Moreover, DOE may not prescribe a standard: (1) For certain equipment, including MHLFs, if no test procedure has been established for the equipment, or (2) if DOE determines by rule that the new or amended standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a new or amended standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven factors:

1. The economic impact of the standard on manufacturers and customers of the equipment subject to the standard;
2. The savings in operating costs throughout the estimated average life of the covered equipment in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered equipment that are likely to result from the imposition of the standard;
3. The total projected amount of energy, or as applicable, water, savings likely to result directly from the imposition of the standard;
4. Any lessening of the utility or the performance of the covered equipment likely to result from the imposition of the standard;
5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard;
6. The need for national energy and water conservation; and
7. Other factors the Secretary of Energy (Secretary) considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

EPCA, as codified, also contains what is known as an "anti-backsliding" provision, which prevents the Secretary from prescribing any new or amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of covered equipment. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States of any covered equipment type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the customer of purchasing equipment complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the customer will receive as a result of the standard, as calculated under the applicable test procedure. See 42 U.S.C. 6295(o)(2)(B)(iii).

Additionally, 42 U.S.C. 6295(q)(1) specifies requirements when promulgating a standard for a type or class of covered equipment that has two or more subcategories. DOE must specify a different standard level than that which applies generally to such type or class of equipment for any group of covered equipment that has the same function or intended use if DOE determines that equipment within such group (A) consumes a different kind of energy from that consumed by other covered equipment within such type (or class); or (B) has a capacity or other performance-related feature that other equipment within such type (or class) does not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of equipment, DOE must consider such factors as the utility to the customer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Federal energy conservation requirements generally supersede state laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of federal preemption for particular state laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6297(d)).

Finally, pursuant to the amendments contained in section 310(3) of EISA 2007, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, are required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for covered equipment after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into the standard, or, if that is not feasible, adopt a separate standard for such energy use for that equipment. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures and standards for MHLFs address standby mode and off mode energy use. However, in this rulemaking, DOE only addresses active mode energy consumption as the equipment included in the scope of coverage only consumes energy in active mode.

B. Background

1. Current Standards

EISA 2007 prescribed the current energy conservation standards for MHLFs manufactured on or after January 1, 2009. (42 U.S.C. 6295(hh)(1)) The current standards are set forth in Table II.1. EISA 2007 excludes from the standards: MHLFs with regulated-lag ballasts, MHLFs with electronic ballasts that operate at 480 volts (V); and MHLFs that (1) are rated only for 150 watt (W) lamps; (2) are rated for use in wet locations; and (3) contain a ballast that is rated to operate at ambient air temperatures higher than 50 °C.

[10] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[11] All references to EPCA in this document refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (Dec. 18, 2012).

TABLE II.1—FEDERAL ENERGY EFFICIENCY STANDARDS FOR MHLFs *

Ballast type	Operated lamp rated wattage range	Minimum ballast efficiency %
Pulse-start	≥150 and ≤500 W	88
Magnetic Probe-start	≥150 and ≤500 W	94
Nonpulse-start Electronic	≥150 and ≤250 W	90
Nonpulse-start Electronic	≥250 and ≤500 W	92

* (42 U.S.C. 6295(hh)(1)).

2. History of Standards Rulemaking for MHLFs

DOE is conducting this rulemaking to review and consider amendments to the energy conservation standards in effect for MHLFs, as required under 42 U.S.C. 6295(hh)(2) and (4). On December 30, 2009, DOE published a notice announcing the availability of the framework document, "Energy Conservation Standards Rulemaking Framework Document for Metal Halide Lamp Fixtures," and a public meeting to discuss the proposed analytical framework for the rulemaking. 74 FR 69036. DOE also posted the framework document on its Web site; this document is available at *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/16*. The framework document described the procedural and analytical approaches that DOE anticipated using to evaluate energy conservation standards for MHLFs, and identified various issues to be resolved in conducting this rulemaking.

DOE held a public meeting on January 26, 2010, during which it presented the contents of the framework document, described the analyses it planned to conduct during the rulemaking, sought comments from interested parties on these subjects, and in general, sought to inform interested parties about, and facilitate their involvement in, the rulemaking. At the meeting and during the period for commenting on the framework document, DOE received comments that helped identify and resolve issues involved in this rulemaking.

DOE then gathered additional information and performed preliminary analyses to help develop potential energy conservation standards for MHLFs. On April 1, 2011, DOE published in the **Federal Register** an announcement (the preliminary analysis notice) of the availability of the preliminary technical support document (the preliminary TSD) and of another public meeting to discuss and receive comments on the following matters: (1) The equipment classes DOE planned to analyze; (2) the analytical framework, models, and tools that DOE was using to evaluate standards; (3) the results of the preliminary analyses performed by DOE; and (4) potential standard levels that DOE could consider. 76 FR 1812 (April 1, 2011). In the preliminary analysis notice, DOE requested comment on these issues. The preliminary TSD is available at *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/16*.

The preliminary TSD summarized the activities DOE undertook in developing standards for MHLFs, and discussed the comments DOE received in response to the framework document. It also described the analytical framework that DOE uses in this rulemaking, including a description of the methodology, the analytical tools, and the relationships among the various analyses that are part of the rulemaking. The preliminary TSD presented and described in detail each analysis DOE performed up to that point, including descriptions of inputs, sources, methodologies, and results.

The public meeting announced in the preliminary analysis notice took place on April 18, 2011. At this meeting, DOE presented the methodologies and results of the analyses set forth in the preliminary TSD. Interested parties discussed the following major issues at the public meeting: (1) Alternative approaches to performance requirements and the various related efficiency metrics; (2) the possibility of including design standards; (3) amendments to the test procedures for metal halide (MH) ballasts to account for multiple input voltages; (4) the cost and feasibility of utilizing electronic ballasts in MHLFs; (5) equipment class divisions; (6) overall pricing methodology; (7) lamp lifetimes; (8) cumulative regulatory burden; (9) shipments; and (10) the possibility of merging the MHLF and the high-intensity discharge (HID) lamp rulemakings.

In August 2013, DOE published a notice of proposed rulemaking (NOPR) in the **Federal Register** proposing new and amended energy conservation standards for MHLFs. In conjunction with the NOPR, DOE also published on its Web site the complete TSD for the proposed rule, which incorporated the analyses DOE conducted and technical documentation for each analysis. The NOPR TSD was accompanied by the LCC spreadsheet, the national impact analysis spreadsheet, and the manufacturer impact analysis (MIA) spreadsheet—all of which are available on DOE's Web site.[12] The proposed standards were as shown in Table II.2.78 FR 51463 (August 20, 2013).

TABLE II.2—ENERGY CONSERVATION STANDARDS PROPOSED IN THE NOPR

Designed to be operated with lamps of the following rated lamp wattage	Indoor/outdoor †	Test input voltage ††	Minimum standard equation ‡ %
≥50 W and ≤100 W	Indoor	480 V	99.4/(1+2.5×P^(−0.55)).‡
≥50 W and ≤100 W	Indoor	All others	100/(1+2.5×P^(−0.55)).
≥50 W and ≤100 W	Outdoor	480 V	99.4/(1+2.5×P^(−0.55)).
≥50 W and ≤100 W	Outdoor	All others	100/(1+2.5×P^(−0.55)).
>100 W and <150 W*	Indoor	480 V	99.4/(1+0.36×P^(−0.30)).
>100 W and <150 W*	Indoor	All others	100/(1+0.36×P^(−0.30)).
>100 W and <150 W*	Outdoor	480 V	99.4/(1+0.36×P^(−0.30)).
>100 W and <150 W*	Outdoor	All others	100/(1+0.36×P^(−0.30)).
≥150 W** and ≤250 W	Indoor	480 V	For ≥150 W and ≤200 W: 88.0. For >200 W and ≤250 W: 0.06×P + 76.0.
≥150 W** and ≤250 W	Indoor	All others	For ≥150 W and ≤200 W: 88.0. For >200 W and ≤250 W: 0.07×P + 74.0.
≥150 W** and ≤250 W	Outdoor	480 V	For ≥150 W and ≤200 W: 88.0 For >200 W and ≤250 W: 0.06×P + 76.0.
≥150 W** and ≤250 W	Outdoor	All others	For ≥150 W and ≤200 W: 88.0. For >200 W and ≤250 W: 0.07×P + 74.0.

[12] All the spreadsheets models developed for this rulemaking proceeding are available at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/16*.

TABLE II.2—ENERGY CONSERVATION STANDARDS PROPOSED IN THE NOPR—Continued

Designed to be operated with lamps of the following rated lamp wattage	Indoor/outdoor †	Test input voltage ††	Minimum standard equation ‡ %
>250 W and ≤500 W	Indoor	480 V	91.0.
>250 W and ≤500 W	Indoor	All others	91.5.
>250 W and ≤500 W	Outdoor	480 V	91.0.
>250 W and ≤500 W	Outdoor	All others	91.5.
>500 W and ≤2000 W	Indoor	480 V	For >500 W to <1000 W: 0.994×(0.0032×P + 89.9). For ≥1000 W to ≤2000 W: 92.5 and may not utilize a probe-start ballast.
>500 W and ≤2000 W	Indoor	All others	For >500 W to <1000 W: 0.0032×P + 89.9. For ≥1000 W to ≤2000 W: 93.1 and may not utilize a probe-start ballast.
>500 W and ≤2000 W	Outdoor	480 V	For >500 W to <1000 W: 0.994×(0.0032×P + 89.9). For ≥1000 W to ≤2000 W: 92.5 and may not utilize a probe-start ballast.
>500 W and ≤2000 W	Outdoor	All others	For >500 W to <1000 W: 0.0032×P + 89.9. For ≥1000 W to ≤2000 W: 93.1 and may not utilize a probe-start ballast.

* Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† DOE's proposed definitions for "indoor" and "outdoor" MHLFs are described in section V.A.2.

†† Input voltage for testing would be specified by the test procedures. Ballasts rated to operate lamps less than 150 W would be tested at 120 V, and ballasts rated to operate lamps ≥150 W would be tested at 277 V. Ballasts not designed to operate at either of these voltages would be tested at the highest voltage for which the ballast is designed to operate.

‡ P is defined as the rated wattage of the lamp that the MHLF is designed to operate.

In the NOPR DOE invited comment, particularly on the following issues: (1) The expanded scope of coverage, (2) the proposed amendments to the test procedure, (3) equipment class divisions, (4) the efficiency levels (ELs) analyzed, (5) the method of estimating magnetically ballasted system input power, (6) the determination to include a design standard that would prohibit the sale of probe-start ballasts in newly sold MHLFs for certain wattages, (7) the derived manufacturer selling prices (MSPs), (8) the equipment class scaling factor for tested input voltage, and (9) the proposed trial standard level (TSL 3). 78 FR 51463 (August 20, 2013).

DOE held a NOPR public meeting on September 27, 2013, to hear oral comments on and solicit information relevant to the proposed rule (hereafter the NOPR public meeting). Interested parties in attendance discussed the following major issues: (1) The compliance date, (2) amendments to the test procedure, (3) scope of the rulemaking, (4) equipment class divisions, (5) impacts on the magnetic ballast footprint, (6) impacts on fixture design, (7) testing and manufacturing variation, and (8) impacts of solid-state lighting market penetration on MHLF shipments.

DOE considered the comments received in response to the NOPR after its publication and at the NOPR public meeting when developing this final rule, and responds to these comments in this notice.

3. Compliance Date

EPCA, as amended by EISA 2007, contains guidelines for the compliance date of the standards amended by this rulemaking. EPCA requires DOE to determine whether to amend the standards in effect for MHLFs and whether any amended standards should apply to additional MHLFs. The Secretary was directed to publish a final rule no later than January 1, 2012 to determine whether the energy conservation standards established by EISA 2007 for MHLFs should be amended, with any amendment applicable to equipment manufactured after January 1, 2015. (42 U.S.C. 6295(hh)(2)(B)) As discussed in section VI.C, DOE has determined it will maintain the three-year interval between the publication date of the final rule in the **Federal Register** and the compliance date.

III. Issues Affecting the Scope of This Rulemaking

A. Additional MHLFs for Which DOE Is Setting Standards

The existing energy conservation standards for MHLFs are established in EPCA through amendments made by EISA 2007. (42 U.S.C. 6295(hh)(1)(A)) The statute excludes from coverage MHLFs with regulated-lag ballasts; electronic ballasts that operate at 480 V; and ballasts that are rated only for (1) use with 150 W lamps, (2) use in wet locations, and (3) operation in ambient air temperatures higher than 50 °C.[13] DOE considered expanding the coverage of its energy conservation standards to include these exempted MHLF types and additional rated lamp wattages. For each previously exempted MHLF type and for all expansions of the covered wattage range, DOE considered potential energy savings, technological feasibility, and economic justification when determining whether to include them in the scope of coverage.

Some stakeholders expressed confusion at the NOPR public meeting, stating that they interpreted this rulemaking as establishing efficiency standards for all metal halide ballasts rather than just ballasts in new metal halide lamp fixtures. The Edison Electric Institute (EEI) contended that the rule is misleading because the title indicates it is a rule for metal halide lamp fixtures when it actually establishes standards for all metal halide ballasts, including replacement ballasts. (EEI, Public Meeting Transcript, No. 48 at pp. 14–15, 67–69)[14] DOE clarifies that the scope of this rulemaking affects all new MHLFs. Ballasts sold with new fixtures after the compliance date must meet or exceed the standards promulgated by this rulemaking. Any ballasts sold on the replacement market do not need to comply with these standards.

Regarding the additional fixtures that DOE proposed including in the scope of coverage, the California Energy Commission (CEC) generally supported the expanded scope for MHLFs DOE proposed in the NOPR. (CEC, No. 52 at p. 3) DOE received no other comment regarding the general approach to expand the scope of coverage and considers specific scope comments in the following sections.

[13] As a point of reference, 50 °C is equivalent to 122 °F.

[14] A notation in the form "EEI, Public Meeting Transcript, No. 48 at pp. 14–15, 67–69" identifies a comment that DOE has received and included in the docket of this rulemaking. This particular notation refers to a comment: (1) Submitted by EEI; (2) in the transcript of the MHLF NOPR public meeting, document number 48 in the docket of this rulemaking; and (3) appearing on pages 14–15 and 67–69 of that transcript.

1. EISA 2007 Exempted MHLFs

a. MHLFs With Regulated-Lag Ballasts

Regulated-lag ballasts are mainly used for specialty applications where line voltage variation is large. Regulated-lag ballasts are designed to withstand significant line voltage variation with minimum wattage variation to the lamp, which results in an efficiency penalty compared to ballasts whose output changes more significantly with line voltage variation. The power regulation provided by regulated-lag ballasts is higher than any other magnetic ballast. To be able to withstand large variations, regulated-lag ballasts are designed to be significantly larger than standard ballasts. Through manufacturer interviews and market research, DOE determined that the size and weight of regulated-lag ballasts limit their use as substitutes in traditional applications. Manufacturers and market research confirmed that their exemption did not lead to a significant market shift to regulated-lag ballasts. Furthermore, DOE's market research found none of this equipment available in major manufacturers' catalogs. The absence of regulated-lag ballasts from catalogs indicates a very small market share and therefore limited potential for significant energy savings. Thus, in the NOPR DOE proposed continuing to exempt MHLFs with regulated-lag ballasts from energy conservation standards.

Universal Lighting Technologies (ULT) and the National Electrical Manufacturers Association (NEMA) agreed with DOE's proposal to continue exempting regulated-lag ballasts from the scope of this rulemaking. NEMA further added that this higher cost technology is used in limited and specific applications, such as heavy industrial, security, and street and tunnel lighting, in order to avoid lamp failures caused by severe voltage dips. (ULT, No. 50 at p. 2; NEMA, No. 56 at p. 5; NEMA, Public Meeting Transcript, No. 48 at p. 48) Agreeing with this description of a limited, niche market and receiving no comments to the contrary, in this final rule DOE exempts regulated-lag ballasts from energy conservation standards.

b. MHLFs With 480 V Electronic Ballasts

In the NOPR, DOE concluded that 480 V electronic ballasts have a very small market share as they are only manufactured by one company and have limited availability from distributors. As a result, DOE determined that there is limited potential for significant energy savings, and in the NOPR proposed continuing to exempt MHLFs with 480 V electronic ballasts from energy conservation standards.

Philips Lighting (Philips), ULT, and NEMA agreed with DOE's decision to exclude 480 V electronic ballasts in the scope of this rulemaking. ULT noted that very few 480 V electronic ballasts are in the market, while Philips commented that 480 V electronic ballasts do not exist at any wattage. (Philips, Public Meeting Transcript, No. 48 at p. 130; ULT, No. 50 at p. 2; NEMA, No. 56 at p. 5) Having received no comments in disagreement, DOE continues to exempt 480 V electronic ballasts from energy conservation standards in this final rule.

c. Exempted 150 W MHLFs

After receiving exemption from energy conservation standards in EISA 2007, shipments of 150 W outdoor MHLFs rated for wet and high-temperature locations increased. Further, some indoor applications use the exempted outdoor MHLFs, negating possible energy savings for indoor 150 W MHLFs. Therefore, in the NOPR DOE concluded that including the currently exempt 150 W MHLFs in the scope of coverage has the potential for significant energy savings. Additionally, as a range of ballast efficiencies exists in commercially available ballasts, DOE found that improving the efficiencies of the ballasts included in these fixtures is technologically feasible and economically justified. Accordingly, in the NOPR DOE proposed including 150 W MHLFs in wet locations and ambient temperatures greater than 50 °C in the scope of this rulemaking.

NEMA, ULT, CEC, and the Southern Company disagreed with DOE's decision to include all 150 W ballasts in the scope of this rulemaking. (NEMA, No. 56 at pp. 5, 12; ULT, No. 50 at pp. 2–3; CEC, No. 52 at p. 3; Southern Company, No. 64 at p. 2; No. 64 at p. 2) NEMA commented that while DOE does have the authority to include this equipment, it must be done in a technologically and economically feasible manner. NEMA stated that the efficiencies adopted in the final rule must be substantially lowered from those proposed in the NOPR to be technologically feasible. (NEMA, No. 56 at pp. 5, 24) In support of this point, ULT and NEMA noted that the industry has not yet been able to create a 150 W MHLF with a magnetic ballast that achieves 88 percent efficiency, which is the minimum efficiency requirement proposed in the NOPR for previously exempt 150 W MHLFs. (ULT, Public Meeting Transcript, No. 48 at pp. 108–109; ULT, No. 50 at pp. 5–6, 23–24; NEMA, No. 56 at p. 13)

In contrast, in a joint comment the Pacific Gas and Electric Company, Southern California Gas Company, San Diego Gas and Electric, and Southern California Edison (hereafter referred to as the California investor-owned utilities or the "CA IOUs") supported DOE's proposal to include previously exempt 150 W MHLFs in the scope of coverage. CA IOUs were unaware of any specific attributes that limit 150 W ballasts from reaching greater efficiency, and believe the lower efficiencies of these ballasts are more likely due to their prior exemption from standards, as there is significant room for improvement. Therefore, CA IOUs supported the inclusion of these ballasts. (CA IOUs, No. 54 at pp. 1–2) Also, in a joint comment the Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, National Consumer Law Center, Natural Resources Defense Council, Northwest Energy Efficiency Alliance, and Northwest Power and Conservation Council (hereafter referred to as the "Joint Comment") supported including 150 W MHLFs previously exempted by EISA 2007 in the scope of this final rule. (Joint Comment, No. 62 at p. 9)

DOE agrees that commercially available magnetic ballasts cannot meet the EISA 2007 specified 88 percent efficiency. However, the 150 W fixtures exempted by EISA 2007 have a range of magnetic ballast efficiencies available below 88 percent and therefore energy conservation standards are technologically feasible. These fixtures can be considered separately from those 150 W fixtures covered by EISA 2007 by separating them into different equipment classes and DOE therefore finds no reason the previously exempt 150 W fixtures should not be covered by this rulemaking. Therefore in this final rule, DOE has included 150 W fixtures rated for use in wet locations and ambient temperatures greater than 50 °C in the scope of coverage.

NEMA, ULT, and Southern Company commented that the inclusion of 150 W ballast efficiency requirements would practically prohibit usage of 150 W magnetic ballasts, thereby forcing the usage of electronic ballasts in new fixtures. (NEMA, No. 56 at p. 6; ULT, No. 50 at pp. 2–3; Southern Company, No. 64 at p. 2) ULT and Southern Company expressed concerns that electronic ballasts for MH lamps are not proven in outdoor applications and are vulnerable to failures due to moisture, temperatures higher than 50 °C, and voltage variations and surges caused by lightning and other natural events. (ULT, No. 50 at pp. 2–3; Southern Company, No. 64 at p. 2)

DOE considered both more efficient magnetic and more efficient electronic ballasts as replacements for ballasts in the previously exempt 150 W fixtures. DOE has determined that, with the proper fixture adjustments, electronic ballasts can be used in the same applications as magnetic ballasts. For detailed discussion of this decision, see section V.A. DOE has concluded that the standard levels adopted in this final rule are economically justified.

General Electric (GE) commented that energy conservation standards for previously exempt 150 W MHLFs could actually increase rather than decrease national energy consumption. GE noted that the purpose of the 150 W exemption from EISA 2007 was to shift the market from 175 W fixtures to 150 W fixtures, thereby saving energy. Thus, GE disagreed with the way DOE analyzed 150 W fixtures and noted that the previously exempt fixtures should not be subject to standards higher than max tech. (GE, Public Meeting Transcript, No. 48 at pp. 135–136)

CA IOUs acknowledged that 150 W ballasts can be a low-wattage replacement for 175 W applications. Accordingly, CA IOUs encouraged increasing efficiency standards for both wattage levels equally, so as not to inadvertently push customers to the higher-wattage alternatives. (CA IOUs, No. 54 at pp. 1–2) CEC agreed, stating that by incentivizing 150 W fixtures through minimal efficiency standards, the market would be driven toward purchasing these lower-wattage fixtures instead of 175 W or 200 W fixtures. (CEC, No. 52 at p. 3)

The Joint Comment noted that while customers may choose to shift between different wattage MHLFs, continuing to exempt 150 W MHLFs is not the best solution. For example, a continued exemption might create market distortions and hinder the transitions to more efficient light-emitting diode (LED) lamps in this

wattage category. (Joint Comment, No. 62 at p. 9) The Joint Comment also stated that even if the inclusion of 150 W fixtures leads to the use of more 175 W or 200 W fixtures, it might not result in more energy consumption as switching to higher-wattage fixtures could also reduce the number of fixtures installed. In situations where the number of fixtures installed is not reduced, additional energy use could be offset by increased ballast efficiency in this wattage bin. In addition, the increased price of the 175 W fixtures provides more disincentive to purchase them over 150 W fixtures. Finally, the Joint Comment argued that if the standards apply to all wattage ranges from 50 W to 500 W, switching from 150 W to a higher-wattage fixture would not be a concern because all fixtures would be subject to the same standards. (Joint Comment, No. 62 at p. 9)

DOE notes that the exemption of certain 150 W fixtures from EISA 2007 resulted in a shift from 175 W to the exempted 150 W fixtures, which resulted in energy savings. In the shipments analysis, DOE considers how different standards for 150 W and 175 W MHLFs may impact customer choices. For example, when the initial first cost for 150 W fixtures exceeds that of 175 W fixtures, the shipments analysis models a shift to 175 W MHLFs. Even with some customers shifting to higher wattage MHLFs, energy conservation standards for 150 W fixtures still result in energy savings due to increased ballast efficiency. In this final rule, DOE has determined that standards for previously exempt 150 W MHLFs are technologically feasible, economically justified, and would result in significant energy savings (see section VII.C for details). Therefore, DOE has included previously exempt 150 W fixtures in the scope of coverage of this rulemaking.

2. Additional Wattages

Based on equipment testing and market research, DOE found in the NOPR that energy conservation standards for MHLFs rated for wattages greater than 50 W and less than 150 W, and MHLFs rated for wattages greater than 500 W, are technologically feasible, economically justified, and would result in significant energy savings. DOE determined that MHLFs rated for wattages greater than 2000 W only served small-market-share applications like graphic arts, ultraviolet (UV) curing, and scanners. Therefore, in the NOPR DOE proposed to include in the scope of coverage 50 W–150 W MHLFs and 501 W–2000 W MHLFs, in addition to the 150 W–500 W MHLFs [15] covered by EISA 2007.

NEMA and ULT opposed the expansion of coverage of this rulemaking to include 50 W–150 W MHLFs. They further commented that coverage of 50 W–100 W MHLFs would require redesign of all magnetic ballasts in that range, which would be nearly equivalent to banning magnetic ballasts. (NEMA, No. 56 at p. 6; ULT, No. 50 at pp. 2–3)

DOE has found MHLFs with a variety of ballast efficiencies in the 50 W–150 W range, including the 50 W–100 W range specifically cited by NEMA and ULT. Therefore, DOE believes energy conservation standards for 50 W–150 W MHLFs are technologically feasible. DOE considered both more efficient magnetic and more efficient electronic ballasts as replacements for ballasts in this rulemaking. DOE has determined that, with the proper fixture adjustments, electronic ballasts can be used in the same applications as magnetic ballasts. For detailed discussion of this decision, see section V.A. Economic impacts of standard levels on individual customers, manufacturers, and the nation are discussed in section VII.B. DOE has concluded that the standard levels adopted in this final rule for 50 W–150 W MHLFs are economically justified and would result in significant energy savings. Therefore, DOE has included 50 W–150 W MHLFs in the scope of coverage for this final rule.

DOE received several comments regarding the inclusion of MHLFs greater than 500 W in the scope of coverage. CA IOUs and Earthjustice supported the expansion of the scope of coverage to include 50 W–2000 W fixtures. (CA IOUs, No. 54 at pp. 1–2; Earthjustice, Public Meeting Transcript, No. 48 at p. 171) CA IOUs commented that because 18 percent of MH ballasts are designed to operate lamps greater than 500 W, there exists an opportunity for significant energy savings. (CA IOUs, No. 54 at pp. 1–2)

In contrast, NEMA and ULT disagreed with the inclusion of MHLFs greater than 500 W, noting that coverage of the 501 W–2000 W range would require redesign of the 750 W fixture family and this would come with significant cost increase. (NEMA, No. 56 at pp. 6–7; ULT, No. 50 at pp. 2–3)

DOE believes that standards for 500 W–1000 W MHLFs are technologically feasible because MHLFs in this wattage range contain ballasts that exhibit a range of efficiencies, indicating it is possible for a standard to improve the efficiency of ballasts already on the market. Specifically, DOE has found 750 W MHLFs with ballasts at multiple efficiencies that span both EL1 and EL2. Furthermore, DOE has analyzed MHLFs in this wattage range and concluded that standards for these MHLFs are economically justified and result in significant energy savings (see section VII.B of this notice for more details). Therefore, DOE includes 500 W–1000 W MHLFs in the scope of coverage for this rulemaking.

NEMA, GE, ULT, Musco Sports Lighting, LLC (Musco Lighting), Venture Lighting International, Inc. (Venture), and OSRAM SYLVANIA Inc. (OSI) all asserted that fixtures greater than 1000 W should not be covered by this rulemaking, as they are only operated in "specialty lighting" applications. They stated that the lamps' limited applications and low hours of operation do not result in appreciable savings opportunities, provide little energy gains at a significant cost, and pose an unjustified burden on manufacturers. (NEMA, Public Meeting Transcript, No. 48 at p. 114; NEMA, No. 56 at pp. 6–7; GE, Public Meeting Transcript, No. 48 at pp. 115, 172; ULT, No. 50 at pp. 2–3; Musco Lighting, Public Meeting Transcript, No. 48 at pp. 118, 180; Musco Lighting, No. 55 at pp. 3–4; Venture, Public Meeting Transcript, No. 48 at p. 170; OSI, Public Meeting Transcript, No. 48 at p. 172) Further, NEMA cited the 2010 U.S. Lighting Market Characterization (2010 LMC),[16] as evidence that stadium and sports lighting, the most common application for fixtures greater than 1000 W, is a niche market, unsuitable for energy savings exploration. Specifically, NEMA noted that in the 2010 LMC, the 839,000 MH lamps in stadium applications represent 2.8 percent of outdoor MH lamps (0.4 percent of all outdoor lamps) and only 1.2 percent of all installed MH lamps (see Table 4.1 in the 2010 LMC). For MH lamps in stadium applications, the average wattage is 1554 W (see Table 4.28 in the 2010 LMC) with an average usage of just 1 hour per day (see Table 4.29 in the 2010 LMC). NEMA agreed with the 2010 LMC that this is a reasonable average usage profile for MH lamps greater than 1000 W. In contrast, typical outdoor MH lamps average 12.1 hours per day ranging from 8.8 hours on building exteriors to 15 hours in parking areas. (NEMA, No. 56 at pp. 6–7)

Musco Lighting pointed out that DOE's decision to not directly analyze 480 V magnetic ballasts due to low shipment volume supported their assertion that 1500 W fixtures should be exempt from energy conservation standards. Musco Lighting specified that as more than 50 percent of their shipments of 1500 W MHLFs contained a 480 V ballast, both MHLF types should be exempt. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 129)

DOE determined that sports lighting, which is the predominant application for lamps above 1000 W, fits the definition of general lighting and is therefore included in the scope of this rulemaking (see the following section III.A.3 for additional discussion). Although these higher wattage MHLFs do not comprise a large percentage of the market, their high wattage could potentially result in significant energy savings. DOE notes that MHLFs greater than 1000 W exist in a variety of efficiencies and therefore standards for these MHLFs are technologically feasible. DOE acknowledges, however, that MHLFs greater than 1000 W have a different cost-efficiency relationship than 501 W to 1000 W MHLFs. Therefore, in this final rule, DOE created a separate equipment class to analyze these MHLFs. See section V.A.2 for additional detail. After considering the economic impacts of standards for MHLFs greater than 1000 W on individual customers, manufacturers, and the nation, DOE has concluded that standards for these MHLFs are not economically justified. Therefore, in this final rule, DOE has not included MHLFs greater than 1000 W in the scope of coverage and has not adopted energy conservation standards for these MHLFs. See section VII for a discussion of the economic impacts.

[15] DOE uses this shorthand to refer to MHLFs with ballasts designed to operate lamps rated greater than or equal to 50 W and less than 150 W, MHLFs with ballasts designed to operate lamps rated greater than 500 W and less than or equal to 2000 W, and MHLFs with ballasts designed to operate lamps rated greater than or equal to 150 W and less than or equal to 500 W, respectively.

[16] U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy. 2010 *U.S. Lighting Market Characterization*. 2010. Available at *http://apps1.eere.energy.gov/buildings/publications/pdfs/ssl/2010-lmc-final-jan-2012.pdf*.

3. General Lighting

EISA 2007 defines the scope of this rulemaking as applying to MHLFs used in general lighting applications. (42 U.S.C. 6291(64)) In section 2 of 10 CFR Part 430, Subpart A, a general lighting application is defined as lighting that provides an interior or exterior area with overall illumination. In the NOPR, DOE proposed to add this definition to 10 CFR Part 431.2,[17] the section of the CFR that relates to commercial and industrial equipment, such as MHLFs. DOE's research indicated that there are a number of applications, such as outdoor sports lighting and airfield lighting, which commonly use MH ballasts of 1000 W to 2000 W and provide general illumination to an exterior area. In the NOPR, DOE proposed that such applications are general lighting applications and are covered by this rulemaking.

ULT, NEMA, GE, Musco Lighting stated that all MHLFs above 1000 W have limited operating hours and are for specialty applications, not general lighting. (ULT, No. 50 at pp. 2–3; NEMA, No. 56 at pp. 6–7; GE, Public Meeting Transcript, No. 48 at p. 115; Musco Lighting, Public Meeting Transcript, No. 48 at p. 118) Earthjustice commented that the definition of "general lighting" refers to overall illumination of an interior or exterior area, not to the hours of use of an application. Therefore, Earthjustice stated that these higher-wattage lamps that serve applications such as sports lighting, parks, and airfields that provide overall illumination to exterior areas should not be considered niche equipment. (Earthjustice, Public Meeting Transcript, No. 48 at pp. 171, 174)

DOE agrees that the higher wattages fall under the CFR definition of general lighting. As mentioned previously, DOE also acknowledges that these lamps have limited operating hours and used these hours of use to calculate their energy savings potential. However, DOE does not believe that low operating hours impacts whether high wattage MHLFs are used in general lighting applications. DOE has determined that sports lighting is a general lighting application because it is "lighting that provides an interior or exterior area with overall illumination." In this final rule, DOE adopts this definition for general lighting application in 10 CFR 431.2.

4. High-Frequency Electronic Ballasts

Electronic ballasts can be separated into two main types, low-frequency electronic (LFE) and high-frequency electronic (HFE). HFE ballasts are electronic ballasts with frequencies greater than or equal to 1000 hertz (Hz). DOE received comment that HFE ballasts should not be included in the scope of coverage based on compatibility issues and the lack of test procedure (DOE's proposed test procedure is discussed in section IV.A).

Venture and NEMA commented that there are no ANSI standards for the HFE ballasts that may be required to meet the analyzed standard levels, and therefore there will be limited MH lamps for use with these ballasts for a substantial period of time. (Venture, Public Meeting Transcript, No. 48 at p. 29; NEMA, No. 56 at p. 9) NEMA elaborated that many MH lamps are not compatible with existing HFE ballasts because of variation in arc tube size and shape. Due to this variation, HFE acoustic resonances can cause arc instability or even lamp failure. (NEMA, No. 44 at p. 6) NEMA specifically noted that high-frequency electronic ballasts are incompatible with the most efficacious lamps (ceramic metal halide). A standard that requires high frequency electronic ballasts could reduce overall energy savings because these ballasts are not compatible with the most efficacious MH lamps. (NEMA, No. 56 at p. 9) Furthermore, a standard that eliminates ballasts capable of operating ceramic metal halide lamps would be a violation of EPCA section 325(o)(4) which prohibits DOE from adopting a standard that interested parties have demonstrated results in the elimination of product features from the market. (NEMA, No. 44 at pp. 6–7) NEMA stated that industry standards for high frequency ballasts and lamps have only just begun to be developed and without these standards there will continue to be limited compatibility between high frequency ballasts and lamps (NEMA, No. 44 at p. 7). Even when acceptable frequency ranges are found, NEMA commented that HFE ballasts can also cause electrode back arcing, leading to shortened lamp life. (NEMA, No. 44 at p. 6)

As in the NOPR, DOE recognizes there are compatibility issues associated with HFE ballasts and some MH lamps, in particular ceramic metal halide (CMH) lamps. A standard that requires HFE ballasts could result in a full or partial elimination of CMH lamps from the market due to these compatibility issues. The elimination of CMH lamps could increase energy usage, as CMH lamps are some of the most efficacious MH lamps on the market. In the NOPR, DOE indicated it would take compatibility issues with HFE ballasts into account when selecting the eventual adopted standard of today's final rule. However, as detailed in section IV.A of this notice, DOE has not adopted a test procedure for HFE ballast, based on the lack of an industry consensus test method for this ballast type. DOE has found that in the absence of an applicable test method for these lamps, HFE ballasts cannot be subject to energy conservation standards. Therefore, DOE has not included HFE ballasts in the scope of coverage of this rulemaking.

5. Outdoor Fixtures

In the NOPR, DOE included both indoor and outdoor MHLFs in the scope of coverage because DOE determined that standards for both types of fixtures were technologically feasible, economically justified, and would result in significant energy savings. Because DOE concluded that indoor and outdoor fixtures had different cost-efficiency relationships, DOE analyzed them in separate equipment classes.

The American Public Power Association (APPA) noted that separating the outdoor and indoor lamps or exempting outdoor lamps is necessary because the usage patterns of outdoor lamps differ immensely from indoor. As the circumstances are different when considering both classes, APPA furthered, it is difficult to understand the effects of proposed efficiency standards on each group. APPA also noted that it may make sense to exempt outdoor fixtures from energy conservation standards because the electronic ballasts will have difficulty in extreme weather conditions. APPA, No. 51 at p. 4; APPA, Public Meeting Transcript, No. 48 at p. 103)

As mentioned previously, in the NOPR DOE determined that standards for both types of fixtures were technologically feasible, economically justified, and would result in significant energy savings. This conclusion is reaffirmed by the analysis in the final rule and DOE therefore includes both indoor and outdoor fixtures in the scope of coverage for this rulemaking. DOE agrees with analyzing outdoor and indoor fixtures separately by placing indoor and outdoor MHLFs into separate equipment classes. While the efficiencies achievable by indoor and outdoor fixtures are the same, the different costs affect the resultant cost-efficiency curves. See section V.A.2 of this notice for details on the equipment classes.

6. Hazardous Locations

Although DOE did not consider exempting fixtures designed for use in hazardous locations in the NOPR, NEMA commented that these fixtures need to be exempt from energy conservation standards. As these fixtures are used in potentially explosive atmospheres and listed to Underwriters Laboratories Inc. standard (UL) 844, any change in ballast size would require the fixture to be redesigned and re-tested, creating a tremendous burden on manufacturers. This is because the redesign, retesting, and relisting of these MHLFs would take significantly longer than three years, and leave this equipment type unavailable for an extended period of time. This would result in serious safety concerns until these fixture types were available again. NEMA also finds it would be very difficult for manufacturers to recoup the investment in standards-induced efficiency improvement for these types of MHLFs due to their limited market. Therefore, NEMA suggested that hazardous location fixtures should be granted an exemption from the rulemaking. (NEMA, No. 56 at p. 14)

As discussed in section V.C.8, the standard levels analyzed in this rulemaking do not require an increase in ballast size. Therefore, DOE does not believe hazardous location fixtures would need to be modified due to a change in ballast size. DOE notes that the vast majority of hazardous location fixtures are specified for use with magnetic ballasts. Therefore, DOE investigated existing fixtures, and the requirements of UL 844, to determine whether higher standards for ballasts, specifically those that require electronic ballast technology, would cause existing hazardous location fixtures to be redesigned and/or retested. After reviewing the UL 844 requirements, DOE found no constraints that would specifically or effectively preclude the use of electronic ballasts. Instead, UL 844 contains explosion protection requirements

[17] The general lighting application definition prescribed by EISA 2007 was previously incorporated into the consumer products section (10 CFR Part 430), but has not yet been added to the commercial and industrial equipment section (10 CFR Part 431).

for a luminaire, including requirements that no part of the fixture reach the thermal ignition temperature of a particulate or gas in the environment. DOE's survey of existing hazardous location fixtures found that these fixtures are commonly rated for use with a type of MH ballast and specific wattage. For example, a hazardous location fixture may be rated for use with a magnetic MH ballast of a given wattage (e.g., a 750 W magnetic MH ballast). Most hazardous location fixtures that are currently available are certified for use with magnetic ballasts, with offerings at a variety of wattages.[18] DOE only identified one hazardous location fixture that was rated for use with electronic ballasts (in this case, a 150 W electronic ballast). DOE was unable to confirm that hazardous location fixtures compatible with electronic ballasts were available at the same wattages as hazardous location fixtures compatible with magnetic ballasts that are currently offered on the market. However, as discussed in section VII.C, DOE is not adopting standards that are expected to require the use of electronic ballast technology. Therefore, DOE does not believe the adopted standards in this rulemaking will require hazardous location fixtures to be redesigned and retested and does not exempt them from the standards adopted in this final rule.

7. Summary of MHLFs for Which DOE Is Setting Standards

EISA 2007 established energy conservation standards for MHLFs with ballasts designed to operate lamps with rated wattages between 150 W and 500 W. As previously discussed, EISA 2007 also exempted three types of fixtures within the covered wattage range from energy conservation standards. In this final rule, DOE extends coverage to MHLFs with ballasts designed to operate lamps rated 50 W–150 W and 501 W–1000 W. DOE also includes one type of previously exempt fixture in the scope of coverage: 150 W MHLFs rated for use in wet locations and containing a ballast that is rated to operate at ambient air temperatures greater than 50 °C. DOE continues to exempt regulated-lag ballasts and 480 V electronic ballasts. For all ballasts included in the scope of coverage, DOE has determined that energy conservation standards are technologically feasible, economically justified, and would result in significant energy savings. As such, DOE adopts standards for these MHLFs in this final rule.

B. Alternative Approaches to Energy Conservation Standards: System Approaches

As discussed in the NOPR, DOE considered several alternatives to establishing energy conservation standards for MHLFs by regulating the efficiency of the ballast contained within the fixture. Specifically, DOE considered a lamp-and-ballast system metric, fixture-level metrics, and the compliance paths specified in California's Title 20 regulations (which are now preempted by federal energy conservation standards in 10 CFR 431.326, 74 FR 12058; March 23, 2009). DOE concluded that, after considering all of these alternate approaches, maintaining the EISA 2007 approach of regulating MHLFs by specifying a minimum ballast efficiency was the most widely accepted, least burdensome approach that would ensure energy conservation standards resulted in energy savings. Therefore, in the NOPR DOE proposed standards for MHLFs by requiring that MHLFs contain ballasts that comply with minimum specified efficiencies. NEMA agreed, citing the increased testing burden associated with testing every combination of lamp and ballast sold in a fixture, and recognizing that the majority of MHLFs are not shipped with a lamp. (NEMA, No. 56 at p. 8) Receiving no comment to the contrary, DOE maintains this approach in this final rule.

C. Standby Mode and Off Mode Energy Consumption

EPCA requires energy conservation standards adopted for covered equipment after July 1, 2010 to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) The requirement to incorporate standby mode and off mode energy use into the energy conservation standards analysis is therefore applicable in this rulemaking.

DOE determined that it is not possible for MHLFs to meet off mode criteria because there is no condition in which the components of an MHLF are connected to the main power source and are not already in a mode accounted for in either active or standby mode. DOE recognizes that MHLFs could be designed with auxiliary control devices that could consume energy in standby mode. However, DOE has yet to encounter such a control device design, or other type of MHLF that uses energy in standby mode, on the market. Therefore, in the NOPR DOE concluded that it cannot establish a standard that incorporates standby mode or off mode energy consumption. Receiving no comment to the contrary, DOE maintains this conclusion in the final rule and does not include standby mode or off mode energy consumption in the standards adopted in this final rule.

IV. General Discussion

A. Test Procedures

1. Current Test Procedures

The current test procedures for MH ballasts and MHLFs are outlined in Subpart S of 10 CFR Part 431. The test conditions, setup, and methodology generally follow the guidance of ANSI C82.6–2005. Testing requires the use of a reference lamp, which is to be driven by the ballast under test conditions until the ballast reaches operational stability. Ballast efficiency for the fixture is then calculated as the measured ballast output power divided by the ballast input power. In the NOPR, DOE considered changes to the test procedure regarding input voltage, the testing of HFE ballasts, and rounding requirements.

2. Test Input Voltage

MH ballasts can be operated at a variety of voltages. The most common voltages are 120 V, 208 V, 240 V, 277 V, and 480 V. Ballasts will also commonly be rated for more than one voltage, such as dual-input-voltage ballasts that can be operated at 120 V or 277 V, or quad-input-voltage ballasts that can be operated at 120 V, 208 V, 240 V, or 277 V. Through manufacturer feedback and testing, DOE found that the specific design of a ballast and the voltage of the lamp operated by the ballast can affect the trend between input voltage and efficiency.

The existing test procedures do not specify the voltage at which a ballast is to be tested, and the majority of ballasts sold are capable of operating at multiple input voltages. Therefore, to ensure consistency among testing and reported efficiencies, DOE considered methods of standardizing this aspect of testing in the NOPR.

a. Average of Tested Efficiency at All Possible Voltages

One method analyzed in the NOPR was testing ballasts at each input voltage at which they are able to operate, and then having a standard for the average of these efficiencies. As averaging the efficiencies could misrepresent the performance of the ballast in its common uses and could increase the testing burden, in the NOPR, DOE did not propose this method. Having received no comments to the contrary, DOE continues to reject using the average of tested efficiency at all possible voltages in this final rule.

b. Posting the Highest and Lowest Efficiencies

A second approach considered in the NOPR was requiring testing at each input voltage and listing the best and worst efficiencies on the MHLF label. DOE found that, similar to averaging efficiencies, this approach would increase the compliance testing burden for manufacturers compared to a requirement to test ballasts only at a single voltage. Therefore, DOE did not propose this method. Having received no comments to the contrary, DOE continues to reject the posting of the highest and lowest efficiencies on an MHLF label in this final rule.

c. Test at Single Manufacturer-Declared Voltage

A third approach considered in the NOPR was that the test procedures should allow testing at a single voltage determined by the manufacturer and declared in the test report. DOE concluded that this approach would not be favorable as the efficiency at the manufacturer-declared voltage and the efficiency at the more commonly used voltages may not be the same, and as such could potentially reduce the energy savings of this rulemaking. Thus, DOE did not propose to test ballast efficiency at a single manufacturer-declared voltage.

GE agreed that a multi-tap ballast should be tested at just one input voltage. Rather than testing at the designated highest voltage, GE stated that it should be up to the manufacturer to choose the voltage at which the ballast was optimally designed for purposes of reporting efficiencies. (GE, Public Meeting Transcript, No. 48 at p. 83)

DOE agrees with testing multi-tap ballasts at a single voltage. DOE's position against allowing manufacturers to declare their testing input voltage stems from concerns

[18] While not comprehensive, DOE identified hazardous location fixtures certified for use with magnetic ballasts that operate lamps with rated wattages between 150 W and 750 W.

that manufacturers could optimize efficiency at a voltage that is most convenient or least expensive, rather than the voltage most commonly used by customers. If optimal efficiency is achieved at a less commonly used voltage, the reported ballast efficiency would not be representative of the ballast efficiency in the ballast's more common applications. If the efficiency at the tested voltage and at the most commonly used voltage are not directly correlated, energy savings could potentially be reduced. For these reasons, DOE rejects the proposal to allow manufacturers to select the voltage at which ballasts are tested in this final rule.

d. Test at Highest Rated Voltage

Another input voltage specification that DOE considered was testing the ballast at the highest voltage possible. However, DOE concluded that a ballast's highest rated voltage is not always its most common input voltage, and therefore testing and enforcing standards at the highest voltage could reduce the potential energy savings of this rulemaking. Accordingly, in the NOPR DOE did not propose to test ballast efficiency at the highest rated voltage. Having received no comments to the contrary, DOE continues to reject testing at the highest rated voltage in this final rule.

e. Test on Input Voltage Based on Wattage and Available Voltages

The final approach analyzed was testing the most common input voltages for each wattage range. This meant, when possible, ballasts less than 150 W are tested at 120 V, ballasts greater than or equal to 150 W are tested at 277 V, and if those specified voltages are unavailable, the ballast is tested at the highest available voltage. DOE concluded that because this proposal only requires testing at one input voltage, it minimizes testing burden. In addition, because the input voltage specification matches the most commonly used voltage, the requirement encourages optimization of efficiency around an input voltage commonly used in practice.

NEMA and ULT agreed with DOE's NOPR proposals regarding the input voltage for testing. (NEMA, No. 56 at p. 8; ULT, No. 50 at p. 4) Having received no comments to the contrary, in this final rule, DOE amends the test procedure to require that ballasts be tested at the following input voltages:

- For ballasts less than 150 W with an available voltage of 120 V, ballasts will be tested at 120 V.
- For ballasts less than 150 W that lack 120 V as an available voltage, ballasts will be tested at the highest available input voltage.
- For ballasts operated at 150 W–2000 W that also have 277 V as an available input voltage, ballasts will be tested at 277 V.
- For ballasts operated at 150 W–2000 W that lack 277 V as an available input voltage, ballasts will be tested at the highest available input voltage.

3. Testing High-frequency Electronic Ballasts

MHLF test procedures reference the 2005 version of ANSI C82.6 for testing both electronic and magnetic MH ballasts. However, ANSI C82.6–2005 does not provide a method for testing HFE ballasts. In the NOPR, DOE found that the instrumentation commonly used for HFE MH ballast testing is the same instrumentation used for electronic fluorescent lamp ballast testing. Therefore, DOE proposed the same instrumentation used in electronic fluorescent lamp ballast testing be used for testing HFE MH ballasts. These proposed requirements specified that once the output frequency of a MH ballast is determined to be greater than or equal to 1000 Hz (the frequency at which DOE defines HFE ballasts) the test procedure instrumentation would be required to include a power analyzer that conforms to ANSI C82.6–2005 with a maximum of 100 picofarads (pF) capacitance to ground and a frequency response between 40 Hz and 1 MHz. The test procedures would also require a current probe compliant with ANSI C82.6–2005 that is galvanically isolated and has a frequency response between 40 Hz and 20 MHz, and lamp current measurement where the full transducer ratio is set in the power analyzer to match the current to the analyzer. The full transducer ratio would be required to satisfy the following equation:

$$\frac{I_{in}}{V_{out}} \times \frac{R_{in}}{R_{in} + R_s}$$

Where:

I_{in} is current through the current transducer;
V_{out} is the voltage out of the transducer;
R_{in} is the power analyzer impedance; and
R_s is the current probe output impedance.

DOE received comment on the lack of compatibility standards between HFE ballasts and MH lamps. NEMA commented that no work has begun on the ANSI C82.6 test procedure standard for HFE ballasts. (NEMA, No. 44 at p. 7) Philips noted that as HFE ballasts do not have testing standards, measurement errors and testing differences could lead to false efficiency values. (Philips, Public Meeting Transcript, No. 48 at p. 70) Similarly, NEMA stated that lack of industry testing standard meant efficiencies are computed using internal test procedures. Therefore, using catalog data gathered from more than one manufacturer combines different test procedures. (NEMA, Public Meeting Transcript, No. 48 at p. 31; NEMA, No. 44 at p. 8) NEMA also noted that labs cannot be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) to submit HFE ballast testing to DOE without a test procedure to accredit to. (NEMA, No. 56 at p. 9) Further, NEMA noted that it is difficult to precisely measure the power of these HFE ballasts at frequencies over 100 kHz, which experience a 2–5 percent measurement uncertainty. With a tenth of a percentage precision on ballast efficiency, it will be very difficult to attain these levels of measurement. (NEMA, Public Meeting Transcript, No. 48 at p. 30; NEMA, No. 44 at p. 8)

DOE agrees that there are no industry test procedures for HFE ballasts. While the addition of instrumentation requirements addresses some concerns, specifications for lamps to be paired with the ballast during testing and a complete test method specific to HFE ballasts (an equivalent document to ANSI C82.6—which covers magnetic ballasts and LFE ballasts, but not HFE ballasts) are not currently available. Therefore, in this final rule, DOE is not adopting any changes to the test procedure for HFE ballasts. As discussed in section III.A.4 of this notice, DOE is not considering standards for HFE ballasts because a test procedure for HFE ballasts does not exist.

4. Rounding Requirements

Through testing, DOE found that testing multiple samples of the same ballast yielded a range of ballast efficiencies typically differing by less than one percent. Because this data introduces both test measurement and sample to sample variation, the test measurement itself should be at least this accurate. Therefore, DOE came to the conclusion that test procedures can resolve differences of less than one percent and rounding to the tenths of a percent would be reasonable. In the NOPR, DOE proposed amending the MH ballast test procedure for measuring and recording input wattage and output wattage to require rounding to the nearest tenth of a watt, and the resulting calculation of efficiency to the nearest tenth of a percent.

ULT, EEI, and NEMA commented that most test equipment for MHLFs is not calibrated to the proposed level of precision. ANSI standards require wattmeters to have 0.5 percent accuracy. (ULT, Public Meeting Transcript, No. 48 at p. 82; EEI, Public Meeting Transcript, No. 48 at p. 85; NEMA, No. 44 at p. 13). Further, NEMA noted that white paper NEMA LSD–63–2012 on variability estimated the tolerance for a sample of four magnetic ballasts to be 4.7 percent when 99 percent confidence factor is required. (NEMA, No. 56 at p. 8) On the contrary, CA IOUs commented that efficiency measurement equipment accurate to plus or minus 0.5 percent is already capable of measuring efficiency to the nearest watt for lamps of 100 W and above, and the nearest tenth of a watt for lamps below 100 W. CA IOUs argued this supports tenths place rounding of an efficiency figure and setting of standards to the tenth of a percent. (CA IOUs, No. 54 at pp. 2–3). Finally, EEI commented that if the difference between EL1 and EL2 is 0.6 percent, and there is a testing tolerance

of plus or minus 1 percent, there could be a classing issue. (EEI, Public Meeting Transcript, No. 48 at p. 159).

DOE reviewed ANSI C82.6–2005 and found that the instrumentation requirements stipulate that watts be measured with 3.5 digits of resolution, with basic accuracy of 0.5 percent. For an efficiency calculation that involves output power divided by input power, 3.5 digits of resolution allows for rounding efficiency to three significant figures (e.g., 0.895 or 89.5 percent) using only three digits. DOE also notes that some manufacturers have submitted compliance data to DOE's certification, compliance, and enforcement (CCE) database rounded to three significant figures and, in response to the NOPR, manufacturers had responded to certain issues using efficiency data rounded to three significant figures. Both of these suggest that manufacturers already have the capability to accomplish these measurements. DOE also considered LSD–63, as suggested by NEMA, but found that it details the population distribution from all sources of variation and did not find that it provides any information regarding the ability to measure the efficiency of an individual ballast to three significant figures. For these reasons, this final rule amends the test procedure to require measuring and calculating ballast efficiency to three significant figures. DOE also adopts energy conservation standards that are specified to three significant figures.

B. Technological Feasibility

1. General

In each standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the equipment that is the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available equipment or in working prototypes to be technologically feasible. 10 CFR 430, subpart C, appendix A, section 4(a)(4)(i).

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, or service; (2) adverse impacts on equipment utility or availability; and (3) adverse impacts on health or safety. Section V.B of this notice discusses the results of the screening analysis for MHLFs, particularly the designs DOE considered, those it screened out, and those that are the basis for the TSLs in this rulemaking. For further details on the screening analysis for this rulemaking, see chapter 4 of the final rule TSD.

2. Maximum Technologically Feasible Levels

When DOE adopts a new or amended standard for a type or class of covered equipment, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such equipment. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible ("max-tech") improvements in energy efficiency for MHLFs, using the design parameters for the most efficient equipment available on the market or in working prototypes. For MHLFs from 50–500 W, the max-tech fixtures use high-grade electronic ballasts. For MHLFs from 501–2000 W, the max-tech fixtures use magnetic ballasts that incorporate high-grade, grain-oriented steel (M6 [19]). (See chapter 5 of the final rule TSD for additional detail.) The max-tech levels that DOE determined for this rulemaking are listed in Table IV.1.

TABLE IV.1—MAX-TECH LEVELS

Equipment class wattage range	Efficiency level *	Efficiency-level equation † %
≥50 and ≤100	EL4	1/(1+0.360×P^(−0.297))
>100 and <150 *	EL4	1/(1+0.360×P^(−0.297))
≥150 ** and ≤250	EL4	1/(1+0.360×P^(−0.297))
>250 and ≤500	EL4	1/(1+0.360×P^(−0.297))
>500 and ≤1000	EL2	For >500 W and ≤750 W: 0.910 For >750 W and ≤1000 W: 0.000104×P+0.832
>1000 and ≤2000	EL2	0.936

* Includes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 watt lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 watt lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† P is defined as the rated wattage of the lamp that the fixture is designed to operate.

C. Energy Savings

1. Determination of Savings

For each TSL, DOE projected energy savings from the products that are the subject of this rulemaking purchased in the 30-year period that begins in the year of compliance with new and amended standards (2017–2046). The savings are measured over the entire lifetime of equipment purchased in the 30-year period.[20] DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the base case. The base case represents a projection of energy consumption in the absence of new or amended mandatory efficiency standards, and considers

[19] The American Iron and Steel Institute type numbers and AK Steel designations for electrical steel grades consist of the letter M followed by a number. The M stands for magnetic material; the number is representative of the core loss of that grade.

[20] In the past DOE presented energy savings results for only the 30-year period that begins in the year of compliance. In the calculation of economic impacts, however, DOE considered operating cost savings measured over the entire lifetime of equipment purchased in the 30-year period. DOE has chosen to modify its presentation of national energy savings to be consistent with the approach used for its national economic analysis.

market forces and policies that affect demand for more efficient equipment. For example, in the base case, DOE models a migration from covered metal halide lamp fixtures to higher efficiency technologies such as high-intensity fluorescent (HIF), induction lights, and LEDs. DOE also models a move to other HID fixtures such as high-pressure sodium, based on data given by manufacturers during the 2010 Framework public meeting. (Philips, Public Meeting Transcript, No. 8 at p. 91)

DOE used its NIA spreadsheet model to estimate energy savings from new and amended standards for the metal halide lamp fixtures that are the subject of this rulemaking. The NIA spreadsheet model (described in section V.G of this notice) calculates energy savings in site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of the savings in the energy that is used to generate and transmit the site electricity. To calculate this quantity, DOE derives annual conversion factors from the model used to prepare the Energy Information Administration's (EIA) *Annual Energy Outlook 2013* (*AEO2013*).

DOE has begun to also estimate full-fuel-cycle energy savings. 76 FR 51282 (August 18, 2011), as amended at 77 FR 49701 (August 17, 2012). The full-fuel-cycle (FFC) metric includes the energy consumed in extracting, processing, and transporting primary fuels, and thus presents a more complete picture of the impacts of energy efficiency standards. DOE's evaluation of FFC savings is driven in part by the National Academy of Science's (NAS) report on FFC measurement approaches for DOE's Appliance Standards Program.[21] The NAS report discusses that FFC was primarily intended for energy efficiency standards rulemakings where multiple fuels may be used by a particular product. In the case of this rulemaking pertaining to metal halide lamp fixtures, only a single fuel—electricity—is consumed by the equipment. DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered equipment. Although the addition of FFC energy savings in the rulemakings is consistent with the recommendations, the methodology for estimating FFC does not project how fuel markets would respond to this particular standards rulemaking. The FFC methodology simply estimates how much additional energy, and in turn how many tons of emissions, may be displaced if the estimated fuel were not consumed by the equipment covered in this rulemaking. It is also important to note that inclusion of FFC savings does not affect DOE's choice of adopted standards.

2. Significance of Savings

As noted above, 42 U.S.C. 6295(o)(3)(B) prevents DOE from adopting a standard for covered equipment unless such standard would result in "significant" energy savings. Although the term "significant" is not defined in the Act, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *Herrington*, 768 F.2d 1355, 1373 (D.C. Cir. 1985), indicated that Congress intended "significant" energy savings in this context to be savings that were not "genuinely trivial." The energy savings for all of the TSLs considered in this rulemaking (presented in section VII.B.3.a) are nontrivial, and, therefore, DOE considers them "significant" within the meaning of section 325 of EPCA.

D. Economic Justification

1. Specific Criteria

EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)) The following sections discuss how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Customers

In determining the impacts of an amended standard on manufacturers, DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period.[22] The industry-wide impacts analyzed include INPV, which values the industry on the basis of expected future cash flows; cash flows by year; changes in revenue and income; and other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual customers, measures of economic impact include the changes in LCC and payback period (PBP) associated with new or amended standards. These measures are discussed further in the following section. For customers in the aggregate, DOE also calculates the national net present value of the economic impacts applicable to a particular rulemaking. DOE also evaluates the LCC impacts of potential standards on identifiable subgroups of customers that may be affected disproportionately by a national standard.

b. Savings in Operating Costs Compared to Increase in Price

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered equipment compared to any increase in the price of the covered equipment that are likely to result from the imposition of the standard (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of equipment (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the equipment. To account for uncertainty and variability in specific inputs, such as equipment lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value. For its analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with amended standards.

The LCC savings and the PBP for the considered ELs are calculated relative to a base case that reflects projected market trends in the absence of amended standards. DOE identifies the percentage of customers estimated to receive LCC savings or experience an LCC increase, in addition to the average LCC savings associated with a particular standard level.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for imposing an energy conservation standard, EPCA requires DOE, in determining the economic

[21] "Review of Site (Point-of-Use) and Full-Fuel-Cycle Measurement Approaches to DOE/EERE Building ApplianceEnergy-Efficiency Standards," (Academy report) was completed in May 2009 and included five recommendations. A copy of the study can be downloaded at: *www.nap.edu/catalog.php?record_id=12670.*

[22] DOE also presents a sensitivity analysis that considers impacts for products shipped in a 9-year period.

justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section V.G, DOE uses the NIA spreadsheet to project national site energy savings.

d. Lessening of Utility or Performance of Equipment

In establishing classes of equipment, and in evaluating design options and the impact of potential standard levels, DOE evaluates standards that would not lessen the utility or performance of the considered equipment. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) The standards adopted in today's final rule will not reduce the utility or performance of the equipment under consideration in this rulemaking. One piece of evidence for this claim includes that magnetic ballast ELs are allowed for every covered MHLF wattage and application, meaning that manufacturers are not required to change the electronic configuration of their current offerings. A second piece of evidence is that commercially available stack height and footprint is being maintained for all ballasts, resulting in no required change from current MHLF size. Another piece of evidence is that no standards were adopted for MHLFs greater than 1000 W, so that all commercially available MHLFs at such wattages are subjected to no mandatory adjustments. Overall, the adopted standards were selected to protect the interest of customers and do not lessen MHLF performance or utility.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of a standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE transmitted a copy of its proposed rule to the Attorney General with a request that the Department of Justice (DOJ) provide its determination on this issue. DOE addresses the Attorney General's determination in this final rule.

f. Need for National Energy Conservation

The energy savings from new and amended standards are likely to provide improvements to the security and reliability of the nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the nation's needed power generation capacity.

The new and amended standards also are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases associated with energy production. DOE reports the emissions impacts from today's standards, and from each TSL it considered, in section VII.B.6 of this notice. DOE also reports estimates of the economic value of emissions reductions resulting from the considered TSLs.

g. Other Factors

EPCA allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII))

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the customer of equipment that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential amended energy conservation standards would have on the payback period for customers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to customers, manufacturers, the nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable-presumption payback calculation is discussed in section VII.B.1 of this final rule.

V. Methodology and Discussion

DOE used two spreadsheets to estimate the impact of the adopted standards. The first spreadsheet calculates LCCs and PBPs of potential new energy conservation standards. The second provides shipments forecasts and then calculates national energy savings and NPV impacts of new energy conservation standards. The Department also assessed manufacturer impacts, largely through use of the Government Regulatory Impact Model (GRIM).

Additionally, DOE uses a version of EIA's National Energy Modeling System (NEMS) to estimate the impacts of energy efficiency standards on electric utilities and the environment. The NEMS model simulates the energy sector of the U.S. economy. The version of NEMS used for appliance standards analysis is called NEMS–BT (BT stands for DOE's Building Technologies Program), and is based on the *AEO2013* version of NEMS with minor modifications.[23] The NEMS–BT accounts for the interactions between the various energy supply and demand sectors and the economy as a whole. For more information on NEMS, refer to *The National Energy Modeling System: An Overview,* DOE/EIA–0581 (98) (Feb. 1998), available at: *tonto.eia.doe.gov/FTPROOT/forecasting/058198.pdf.*

As a basis for this final rule, DOE has continued to use the approaches explained in the NOPR. DOE used the same general methodology as applied in the NOPR, but revised some of the assumptions and inputs for the final rule in response to public comments. The following sections discuss these revisions.

A. Market and Technology Assessment

1. General

When completing an energy conservation standards rulemaking, DOE develops information that provides an overall picture of the market for the equipment concerned, including the purpose of the equipment, the industry structure, and the market characteristics. This activity includes both quantitative and qualitative assessments based on publicly available information. The subjects addressed in the market and technology assessment for this rulemaking include: equipment classes and manufacturers; historical

[23] The EIA does not approve use of the name "NEMS" unless it describes an *AEO* version of the model without any modification to code or data. Because the present analysis entails some minor code modifications and runs the model under various policy scenarios that deviate from *AEO* assumptions, the name "NEMS–BT" refers to the model as used here.

shipments; market trends; regulatory and non-regulatory programs; and technologies or design options that could improve the energy efficiency of the equipment under examination. See chapter 3 of the final rule TSD for further discussion of the market and technology assessment.

2. Equipment Classes

When evaluating and establishing energy conservation standards, DOE divides covered equipment into equipment classes by the type of energy used or by capacity or other performance-related features that justifies a different standard. In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility to the customer of the feature and other factors DOE determines are appropriate. (42 U.S.C. 6295(q)) DOE then considers separate standard levels for each equipment class based on the criteria set forth in 42 U.S.C. 6295(o). In the NOPR, DOE proposed to divide equipment classes by input voltage, rated lamp wattage, and designation for indoor versus outdoor applications.

a. Input Voltage

MHLFs are available in a variety of input voltages (most commonly 120 V, 208 V, 240 V, 277 V, and 480 V), and the majority of fixtures are equipped with ballasts that are capable of operating at multiple input voltages (for example, quad-input-voltage ballasts are able to operate at 120 V, 208 V, 240 V, and 277 V). DOE determined that input voltage represents a feature affecting consumer utility as certain applications demand specific input voltages. DOE's ballast testing did not indicate a prevailing relationship (*e.g.*, higher voltages are not always more efficient) between discrete input voltages and ballast efficiencies, with one exception. In the NOPR, DOE found that ballasts tested at 480 V were less efficient on average than ballasts tested at 120 V or 277 V.

As discussed in section IV.A of this final rule, MH ballasts will be tested at a single input voltage based on the lamp wattage operated by the ballast. Ballasts that operate lamps less than 150 W shall be tested at 120 V, and all others shall be tested at 277 V, unless the ballast is incapable of operating at the specified input voltage; in that case, the ballast shall be tested at the highest input voltage possible. Because dedicated 480 V ballasts have a distinct utility in that certain applications require 480 V operation and a difference in efficiency relative to ballasts tested at 120 V and 277 V, in the NOPR DOE proposed separate equipment classes for ballasts tested at 480 V (in accordance with the test procedure).

Philips noted that when manufacturing multi-tap magnetic ballasts, each tap must be precisely placed. The voltage variation in each tap makes it more difficult for multi-tap ballasts to meet efficiency requirements than ballasts with dedicated voltage. (Philips, Public Meeting Transcript, No. 48 at p. 99) NEMA, ULT, and Southern Company supported a separate equipment class for dedicated 480 V ballasts. (NEMA, No. 56 at p. 12; ULT, No. 50 at p. 5; Southern Company, No. 64 at p. 2)

DOE acknowledges that the existence of multiple voltage taps could cause multi-tap ballasts to be less efficient than dedicated voltage ballasts. However, DOE's testing of commercially available ballasts did not identify this trend. Rather, DOE's test results indicated that the only obvious relationship between input voltage and ballast efficiency is that ballasts tested at 480 V were less efficient on average than ballasts tested at 120 V or 277 V. As stated above, DOE believes that input voltage offers unique utility because certain applications require specific input voltages. Therefore, in this final rule, DOE creates a separate equipment class for ballasts that are tested at 480 V.

b. Lamp Wattage

As lamp wattage increases, lamp-and-ballast systems generally produce increasing amounts of light (lumens). Because certain applications require more light than others, wattage often varies by application. For example, low-wattage (less than 150 W) lamps are typically used in commercial applications for general lighting. Medium-wattage (150 W–500 W) lamps are commonly used in warehouse, street, and general commercial lighting. High-wattage (greater than 500 W) lamps are used in searchlights, stadiums, and other applications that require powerful white light. Because different applications require different amounts of light and the light output of lamp-and-ballast systems is typically reflected by the wattage, wattage affects consumer utility. Additionally, the wattage of a lamp operated by a ballast is correlated with the ballast efficiency; ballast efficiency generally increases as lamp wattage increase. Because wattage affects consumer utility and has a strong correlation to efficiency, DOE determined in the NOPR that separate equipment classes based on wattage were warranted.

DOE found that even within a designated wattage range (such as 101 W–150 W), the potential efficiencies ballasts can achieve is not constant, but rather varies with wattage. Thus for certain wattage bins, instead of setting a constant efficiency standard, DOE used an equation-based energy conservation standard (see section V.C). DOE combined the wattage bins and equations rather than using a single equation spanning all covered wattages for two reasons. First, the range of ballast efficiencies considered can differ significantly by lamp wattage, making it difficult to construct a single continuous equation for ballast efficiency from 50 W to 2000 W. This efficiency difference can be attributed to the varying cost of increasing ballast efficiency for different wattages and the impact of legislated (EISA 2007) standards that affect only some wattage ranges. Second, different wattages often serve different applications and have unique cost-efficiency relationships. Analyzing certain wattage ranges as separate equipment classes allows DOE to establish the energy conservation standards that are cost-effective for every wattage.

In the NOPR, DOE proposed to define MHLF equipment classes by the following rated lamp wattage ranges: 50 W–100 W, 101 W–150 W, 150 W–250 W, 251 W–500 W, and 501 W–2000 W.[24] As discussed previously in section III.A.1, there is an existing EISA 2007 exemption for ballasts rated for only 150 W lamps, used in wet locations, and that operate in ambient air temperatures higher than 50 °C. This exemption has led to a difference in the commercially available efficiencies for ballasts that are contained within fixtures exempted versus not exempted from EISA 2007. The exempted fixtures have ballasts with a range of efficiencies similar to ballasts that operate lamps less than 150 W. Fixtures not exempted by EISA 2007 have ballasts that follow efficiency trends representative of ballasts greater than 150 W. As a result, DOE proposed that 150 W MHLFs previously exempted by EISA 2007 be included in the 101 W–150 W range, while 150 W MHLFs subject to EISA 2007 standards continue to be included in the 150 W–250 W range.

[24] DOE uses this shorthand to refer to MHLFs designed to operate lamps rated at equal to or greater than 50 W and equal to or less than 100 W, greater than 100 W and less than 150 W (however, including MHLFs designed to operate lamps rated at 150 W and exempted from EISA 2007), equal to or greater than 150 W and less than or equal to 250 W, greater than 250 W and less than or equal to 500 W, and greater than 500 W and less than or equal to 2000 W, respectively.

ULT and NEMA stated that industry data shows ballast losses are significantly higher in 150 W ballasts relative to 175 W to 500 W ballasts due to the increased lamp current in 150 W MHLFs. (ULT, Public Meeting Transcript, No. 48 at p. 108; ULT, No. 50 at pp. 5–6, 23; NEMA, No. 56 at p. 13) ULT explained that for 150 W–175 W fixtures, the lower the wattage, the larger the ballast needed to maintain efficiency. ULT noted that this relationship is the net effect of three main factors: (1) Higher lamp current, (2) increased impedance, and (3) decreased wire cross-section. In conjunction, these factors make it impossible to have an 88 percent efficient 150 W ballast on a 3.25 inch by 3.75 inch (commonly referred to as a "3x4") frame. (ULT, No. 50 at pp. 23–24) ULT believed that 150 W fixtures could belong to the lower wattage bin; otherwise, the proposed standards would result in a ban of magnetic autotransformer 150 W ballasts. (ULT, No. 50 at p. 5)

DOE agrees with ULT and NEMA that 150 W ballasts have a lower maximum achievable efficiency relative to 175 W ballasts because of the resistive losses characteristic to ballasts at 150 W. Commercially, DOE also found that 150 W ballasts have a range of efficiencies similar to wattages below 150 W. Both of these trends support 150 W fixtures being categorized in separate equipment classes than 175 W fixtures. While DOE continues to group 150 W fixtures covered by EISA 2007 in the 150 W–250 W equipment class, in this final rule DOE maintains the NOPR approach to group 150 W fixtures previously exempt by EISA 2007 in the 101 W–150 W equipment class.

NEMA proposed that DOE establish a separate equipment class for 575 W ballasts but did not provide supporting detail for this proposal. (NEMA, No. 56 at p. 17) DOE examined the efficiency distribution of 575 W ballasts and found that efficiency varied in a manner similar to that of other ballasts within the 500 W to 1000 W wattage range. DOE is unaware of significant differences in the cost-efficiency relationship, consumer utility, or application of 575W fixtures relative to 1000 W fixtures, and therefore is not establishing a separate equipment class for these MHLFs. DOE continues to group all 501 W–1000 W MHLFs in one wattage bin, using 1000 W fixtures as representative of the entire class.

Musco Lighting disagreed with the grouping of fixtures in the 501 W–2000 W range. Musco Lighting stated that there are significant differences between the markets and applications of 1500 W and 1000 W MHLFs, and, accordingly, they should not be grouped together. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 107) Musco Lighting commented that 1500 W fixtures should not be in the same equipment class as 1000 W fixtures. Musco Lighting commented that a majority of 1500 W fixtures operate at 480 V input, which distinguishes them from other equipment classes. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 129) Musco Lighting further commented that annual operating hours should be taken into account so that MHLFs used in applications with very different operating hours would not be included in the same equipment class. Musco Lighting gave the example of sports lighting having much fewer operating hours than indoor warehouse lighting. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 161)

Upon further review, DOE agrees that there are differences between 1500 W and 1000 W fixtures. DOE determined that the trend between increasing wattage and increasing efficiency found from 501 W–1000 W did not continue above 1000 W. DOE found that above 1000 W, efficiency increased to a lesser extent with increased wattage. This is consistent with the NOPR analysis, in which different equations were used above and below 1000 W. DOE also found that lamp lifetime and annual operating hours are much shorter for 1500 W fixtures relative to 1000 W fixtures because 1500 W fixtures are predominantly used in sports lighting. This causes 1500 W fixtures to have different cost-efficiency relationships relative to 1000 W fixtures. There is also a different cost-efficiency relationship based on the MSP of the fixtures themselves, representing a different portfolio of applications used from 501–1000 W and above 1000 W. Therefore, DOE determined that separate equipment classes should be established for 501 W–1000 W and 1001 W–2000 W fixtures.[25]

In summary, DOE established MHLF equipment classes by the following rated lamp wattage bins: 50 W–100 W, 101 W–150 W, 150 W–250 W, 251 W–500 W, 501 W–1000 W, and 1001 W–2000 W. DOE maintained that 150 W fixtures previously exempted by EISA 2007 are included in the 101 W–150 W range, while 150 W fixtures subject to EISA 2007 standards are included in the 150 W–250 W range.

[25] DOE uses this shorthand to refer to MHLFs designed to operate with lamps rated at greater than 500 W and less than or equal to 1000 W, and greater than 1000 W and less than or equal to 2000 W, respectively.

c. Fixture Application

MHLFs are used in a variety of applications such as parking lots, roadways, warehouses, big-box retail, and flood lighting. Although the fixture size, shape, and optics are often tailored to the application, generally the same type of ballast is utilized for most of the applications. DOE found in the NOPR, however, that indoor and outdoor MHLFs are subject to separate cost-efficiency relationships, specifically at the electronic ballast levels.

As outdoor applications can be subject to large voltage transients, MHLFs in such applications require 10 kV voltage transient protection. Magnetic MH ballasts are typically resistant to voltage variations of this magnitude, while electronic MH ballasts are generally not as resilient. Therefore, in order to meet this requirement, electronic ballasts in outdoor MHLFs would need either (1) an external surge protection device or (2) internal transient protection of the ballast using metal-oxide varistors (MOVs) in conjunction with other inductors and capacitors.

DOE also noted that indoor fixtures can require the inclusion of a 120 V auxiliary tap. This output is used to operate an emergency incandescent lamp after a temporary loss of power while the MH lamp is still too hot to restart. These taps are generally required for only one out of every ten indoor lamp fixtures. A 120 V tap is easily incorporated into a magnetic ballast due to its traditional core and coil design, and incurs a negligible incremental cost. Electronic ballasts, though, require additional design to add this 120 V auxiliary power functionality.

These added features impose an incremental cost to the ballast or fixture (further discussed in section V.C.12 of this notice). As these incremental costs could affect the cost-effectiveness of fixtures for indoor versus outdoor applications, in the NOPR DOE proposed separate equipment classes for indoor and outdoor fixtures.

DOE proposed that outdoor fixtures be defined as those that (1) are rated for use in wet locations and (2) have 10 kV of voltage transient protection. DOE proposed to define the wet location rating as specified by the National Fire Protection Association (NFPA) 70–2002,[26] section 410.10(A) or UL 1598

[26] The NFPA 70–2002 states that fixtures installed in wet or damp locations shall be installed such that water cannot enter or accumulate in wiring components, lampholders, or other electrical parts. All fixtures installed in wet locations shall be marked, "Suitable for Wet Locations." All fixtures installed in damp locations shall be marked

Continued

Wet Location Listed.[27] Providing two possible definitions will reduce the compliance burden as many manufacturers are already familiar with one or both of these ratings (the NFPA 70–2002 definition was included in EISA 2007 and both are used in California energy efficiency regulations). For 10 kV voltage transient protection, DOE proposed to use the 10 kV voltage pulse withstand requirement from ANSI C136.2–2004.

APPA agreed with separating equipment classes for indoor and outdoor fixtures, as they have separate uses that create differences in the frequency and length of use. APPA stated that because the circumstances are different when considering both classes, it is difficult to understand the effects of proposed efficiency standards on each group. (APPA, No. 51 at p. 4; APPA, Public Meeting Transcript, No. 48 at p. 103) Conversely, NEMA noted that separate equipment classes for indoor and outdoor fixtures could be problematic as, at the ballast level, there is no way of knowing whether equipment will be used indoors or outdoors. (NEMA, No. 56 at p. 14) Acuity Brands Lighting, Inc. (Acuity) commented that fixture application should also take into account the probability of transient voltages and extreme conditions, even in indoor applications. (Acuity, Public Meeting Transcript, No. 48 at p. 162) NEMA and ULT suggested combining indoor and outdoor equipment classes, except for electronic ballasts, as fewer classes will mean fewer reporting requirements. NEMA acknowledged that this will conflict with DOE's desire to encourage electronic ballasts in outdoor applications. (NEMA, No. 56 at p. 9; ULT, No. 50 at p. 4)

DOE believes that indoor and outdoor MHLFs should be placed into separate equipment classes. While the efficiencies achievable indoors and outdoors are the same, the different costs between indoor and outdoor fixtures result in different cost-efficiency curves. When electronic ballasts are used in outdoor applications, they require additional transient protection because of the potential for voltage surges in outdoor locations. Indoor fixtures with electronic ballasts also have an added cost to provide 120 V auxiliary power functionality for use in the event of a power outage. Both of these cost adders are discussed in more detail in section V.C.12. As these costs adders differ based on a fixture being used indoors or outdoors, the cost-efficiency relationships differ based on indoor or outdoor application, and therefore separate equipment classes are warranted. Thus, in this final rule DOE establishes separate equipment classes for indoor and outdoor fixtures. DOE defines outdoor fixtures as those that (1) are rated for use in wet locations and (2) have 10 kV of voltage transient protection. Conversely, fixtures that do not meet these requirements will be defined as indoor fixtures. DOE continues to use the wet location rating definition from the National Fire Protection Association 70–2002, section 410.10(A) or UL 1598 Wet Location listing.

d. Electronic Configuration

Of the two MH ballast types (electronic and magnetic), magnetic ballasts are currently more common, making up more than 90 percent of MH ballast shipments. Magnetic ballasts typically use transformer-like copper or aluminum windings on a steel or iron core. The newer electronic ballasts, which are more efficient but less common, rely on integrated circuits, switches, and capacitors or inductors to control current and voltage to the lamp. Both electronic and magnetic ballasts are capable of producing the same light output and, with certain modifications (*e.g.,* thermal management, transient protection, 120 V auxiliary power functionality), can be used interchangeably in all applications. In the NOPR, DOE concluded that electronic configuration and circuit type do not affect consumer utility. With the necessary design alterations, electronic ballasts can provide the same utility as any magnetic ballast circuit type. Because electronic ballasts are typically more efficient than magnetic ballasts, utility is not lost with increasing efficiency. Therefore, DOE did not propose to define equipment classes based on electronic configuration.

ULT stated that electronic HID ballasts were originally intended for indoor, niche purposes. Therefore, automatically expecting that electronic MH ballasts would be able to perform in outdoor conditions, including applications subjected to wind, extreme temperature, and transient surges, is not reasonable. ULT noted that electronic ballasts' vulnerability in outdoor applications is known throughout the industry. (ULT, Public Meeting Transcript, No. 48 at p. 52)

NEMA also disagreed with DOE not dividing equipment classes by electronic configuration. NEMA stated that performance requirements should be separated for electronic and magnetic ballasts to avoid an enormous burden on the industry. (NEMA, No. 56 at p. 12, 24) NEMA commented that they disagreed with DOE's suggestion that an electronic ballast is a design option for a magnetic ballast, as they are completely different technologies. (NEMA, No. 56 at p. 14).

DOE has determined that these electronic ballasts, when fitted in an appropriate fixture, can be used in the same applications as magnetic ballasts. As mentioned in the previous section, various protections will be required for electronic ballasts in these applications. See section V.C.8.b for more detail about the feasibility of electronic ballasts as more efficient replacements for magnetic ballasts. After adjusting outdoor fixture prices to account for the modifications necessary to incorporate electronic ballasts, DOE has found that electronic ballasts can be reliably used in the same outdoor applications as magnetic ballasts. Therefore, DOE did not find that magnetic ballasts provided a unique utility over electronic ballasts. Thus, in this final rule, DOE included electronic and magnetic ballasts in the same equipment class.

e. Circuit Type

NEMA disagreed with DOE not dividing equipment classes by circuit type, citing the fluorescent lamp ballast rule as precedent. (NEMA, No. 56 at pp. 12, 24) ULT and NEMA proposed three different technology classes; magnetic series reactors, magnetic autotransformers, and electronic. (ULT, No. 50 at p. 5; NEMA, No. 44 at p. 17) NEMA explained the need for dividing equipment classes in this way by describing the technologies' different utilities and relationships to efficiency. Specifically, NEMA stated that series reactors circuits are the most efficient, although they do not offer any power regulation. Power factor correction is weak with this ballast type, and high power factor increases total harmonic distortion. This circuit type only works for lamps that require an open circuit voltage lower than the mains. It results in an increased inrush and current, and reduced maximum number of lamps per circuit. (NEMA, No. 44 at p. 18) Autotransformer ballasts may be used on various mains voltages, and the ballast open circuit voltage may be higher than the mains voltage. Constant-wattage autotransformer (CWA) designs

"Suitable for Wet Locations" or "Suitable for Damp Locations."

[27] UL Standard Publication 1598 defines a wet location is one in which water or other liquid can drip, splash, or flow on or against electrical equipment. A wet location fixture shall be constructed to prevent the accumulation of water on live parts, electrical components, or conductors not identified for use in contact with water. A fixture that permits water to enter the fixture shall be provided with a drain hole.

include a secondary coil and operate with lower harmonic distortion. They offer better power regulation than series reactors and are highly reliable. (NEMA, No. 44 at p. 19) Electronic circuits are typically less reliable than autotransformer circuits, but operate with similar energy efficiency to series reactors. (NEMA, No. 44 at p. 20)

DOE agrees that within magnetic ballasts there are multiple circuit types, such as reactor and autotransformer. However, DOE has found that electronic ballasts can provide the same utility as any magnetic circuit type and can be substituted in all applications, while being generally more efficient than all magnetic ballasts. DOE also notes that all of the magnetic ELs in this final rule are determined by autotransformer magnetic ballasts, as autotransformer ballasts are the most common type on the market. Because reactor ballasts are typically more efficient than autotransformer ballasts, DOE found that setting a magnetic ballast EL based on autotransformer efficiency would not prohibit reactor ballasts. For these reasons, DOE did not find it necessary in this final rule to separate equipment classes by circuit type.

f. Summary

DOE developed equipment classes in this final rule using three class-setting factors: input voltage, rated lamp wattage, and fixture application. DOE presents the resulting equipment classes in Table V.1

TABLE V.1—MHLF EQUIPMENT CLASSES TABLE

Designed to be operated with lamps of the following rated lamp wattage	Indoor/outdoor †	Input voltage type‡
≥50 W and ≤100 W	Indoor	Tested at 480 V.
≥50 W and ≤100 W	Indoor	All others.
≥50 W and ≤100 W	Outdoor	Tested at 480 V.
≥50 W and ≤100 W	Outdoor	All others.
>100 W and <150 W*	Indoor	Tested at 480 V.
>100 W and <150 W*	Indoor	All others.
>100 W and <150 W*	Outdoor	Tested at 480 V.
>100 W and <150 W*	Outdoor	All others.
≥150 W** and ≤250 W	Indoor	Tested at 480 V.
≥150 W** and ≤250 W	Indoor	All others.
≥150 W** and ≤250 W	Outdoor	Tested at 480 V.
≥150 W** and ≤250 W	Outdoor	All others.
>250 W and ≤500 W	Indoor	Tested at 480 V.
>250 W and ≤500 W	Indoor	All others.
>250 W and ≤500 W	Outdoor	Tested at 480 V.
>250 W and ≤500 W	Outdoor	All others.
>500 W and ≤1000 W	Indoor	Tested at 480 V.
>500 W and ≤1000 W	Indoor	All others.
>500 W and ≤1000 W	Outdoor	Tested at 480 V.
>500 W and ≤1000 W	Outdoor	All others.
>1000 W and ≤2000 W	Indoor	Tested at 480 V.
>1000 W and ≤2000 W	Indoor	All others.
>1000 W and ≤2000 W	Outdoor	Tested at 480 V.
>1000 W and ≤2000 W	Outdoor	All others.

* Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A);); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A);); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† DOE's proposed definitions for "indoor" and "outdoor" MHLFs are described in section V.A.2.c.

‡ Input voltage for testing would be specified by the test procedures. Ballasts rated to operate lamps less than 150 W would be tested at 120 V, and ballasts rated to operate lamps ≥150 W would be tested at 277 V. Ballasts not designed to operate at either of these voltages would be tested at the highest voltage the ballast is designed to operate. See section IV.A for further detail.

B. Screening Analysis

For the screening analysis, DOE consults with industry, technical experts, and other interested parties to determine which technology options to consider further and which to screen out. Appendix A to subpart C of 10 CFR Part 430, "Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products" (the Process Rule), sets forth procedures to guide DOE in its consideration and promulgation of new or revised energy conservation standards. These procedures elaborate on the statutory criteria provided in 42 U.S.C. 6295(o) and, in part, eliminate problematic technologies early in the process of prescribing or amending an energy conservation standard. In particular, sections 4(b)(4) and 5(b) of the Process Rule provide guidance to DOE for determining which design options are unsuitable for further consideration:

Technological feasibility. DOE will consider technologies incorporated in commercial products or in working prototypes to be technologically feasible.

Practicability to manufacture, install, and service. If mass production and reliable installation and servicing of a technology in commercial products could be achieved on the scale necessary to serve the relevant market at the time the standard comes into effect, then DOE will consider that technology practicable to manufacture, install, and service.

Adverse impacts on product utility or product availability. If DOE determines a technology would have significant adverse impacts on the utility of the product to significant subgroups of consumers, or would result in the unavailability of any covered equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as equipment generally available in the United States

at the time, it will not consider this technology further.

Adverse impacts on health or safety. If DOE determines that a technology will have significant adverse impacts on health or safety, it will not consider this technology further.

In the NOPR, DOE screened out one technology option: laminated sheets of amorphous steel. For magnetic metal halide ballasts, DOE found one method of decreasing transformer losses is to create the core of the inductor from laminated sheets of amorphous steel, insulated from each other. DOE screened out amorphous steel technology because it failed to pass the "practicable to manufacture, install, and service" criterion, and using amorphous steel could have adverse impacts on consumer utility because increasing the size and weight of the ballast may limit the places a customer could use the ballast. DOE received no comments to the contrary, and thus continues to screen out amorphous steel in the final rule.

DOE identified the design options listed in Table V.2 as technologies that could improve MHLF ballast efficiency and pass the screening criteria discussed above. For further details on these design options, see chapter 3 of the final rule TSD.

TABLE V.2—METAL HALIDE LAMP FIXTURE DESIGN OPTIONS

Ballast type	Design option		Description
Magnetic	Improved Core Steel		Use a higher grade of electrical steel, including grain-oriented silicon steel, to lower core losses.
	Copper Wiring		Use copper wiring in place of aluminum wiring to lower resistive losses.
	Increased Stack Height		Add steel laminations to lower core losses.
	Increased Conductor Cross Section		Increase conductor cross section to lower winding losses.
	Electronic Ballast		Replace magnetic ballasts with electronic ballasts.
Electronic	Improved Components.	Magnetics	Use grain-oriented or amorphous electrical steel to reduce core losses.
			Use optimized-gauge copper or litz wire to reduce winding losses.
			Add steel laminations to lower core losses.
			Increase conductor cross section to lower winding losses.
		Diodes	Use diodes with lower losses.
		Capacitors	Use capacitors with a lower effective series resistance and output capacitance.
		Transistors	Use transistors with lower drain-to-source resistance.
	Improved Circuit Design.	Integrated Circuits.	Substitute discrete components with an integrated circuit.

C. Engineering Analysis

1. Approach

The engineering analysis develops cost-efficiency relationships depicting the manufacturing costs of achieving increased ballast efficiency. DOE applies two methodologies to estimate manufacturing costs for the engineering analysis: (1) The design-option approach, which provides the incremental costs of adding the design options discussed in section V.B of this notice to improve the efficiency of a baseline model; and (2) the efficiency-level approach, which estimates the costs of achieving increases in ELs through ballast efficiency testing, manufacturer catalogs, and teardowns. Details of the engineering analysis are in chapter 5 of the final rule TSD. The following discussion summarizes the general steps of the engineering analysis:

Determine Representative Equipment Classes. When multiple equipment classes exist, to streamline testing and analysis, DOE selects certain classes as "representative," primarily because of their high market volumes. DOE then scales the ELs from representative equipment classes to those equipment classes it does not analyze directly.

Determine Representative Wattages. Within each representative equipment class, DOE also selects a particular wattage fixture as "representative" of the wattage range, primarily because of their high market volumes. In this final rule, DOE assigns only one representative wattage per representative equipment class.

Representative Fixture Types. To calculate the typical cost of a fixture at each representative wattage, DOE selects certain types of fixtures to analyze as representative.

Select Baseline Units. DOE establishes a baseline unit for each representative wattage. The baseline unit has attributes (circuit type, input voltage capability, electronic configuration) typical of ballasts used in fixtures of that wattage. The baseline unit also has the lowest (baseline) efficiency for each representative wattage. DOE measures changes resulting from potential amended energy conservation standards compared with this baseline. For fixtures subject to existing federal energy conservation standards, a baseline unit is a MHLF with a commercially available ballast that just meets existing standards. If no standard exists for a fixture, the baseline unit is the MHLF at a representative wattage with a ballast with the lowest tested ballast efficiency that is sold. To determine energy savings and changes in price, DOE compares each higher EL with the baseline unit.

To determine the ballast efficiency, DOE tested a range of MH ballasts from multiple ballast manufacturers. In some cases, when test data was unavailable, DOE used efficiency values listed in manufacturer catalog data sheets. Appendix 5A of the final rule TSD presents the test results. When necessary, DOE selects more than one baseline for a representative wattage to ensure consideration of different fixture and ballast types and their associated customer economics.

Select More-Efficient Units. DOE selected both commercially available MHLFs and modeled MHLFs with higher-than-baseline-efficiency ballasts as replacements for each baseline model in each representative equipment class. In general, DOE can identify the design options associated with each more-efficient ballast model by considering the design options that meet the criteria of the screening analysis (chapter 4 of the final rule TSD). For electronic ballasts, where design options cannot be identified for that class by the product number or catalog description, DOE

conducts testing to determine their efficiency. Appendix 5A of the final rule TSD presents these test results. These ballast efficiencies were calculated according to the MH ballast test procedures (10 CFR 431.324), unless otherwise specified. DOE estimates the design options likely to be used to achieve a higher efficiency based on information gathered during manufacturer interviews and information presented in ballast catalogs.

Determine Efficiency Levels. DOE develops ELs based on: (1) The design options associated with the equipment class studied and (2) the max-tech EL for that class. As previously noted and as discussed in section IV.B.2, DOE's ELs are based on test data collected from commercially available equipment, catalog data, manufacturer input, and ballast modeling.

Conduct Price Analysis. DOE generated a bill of material (BOM) by disassembling multiple manufacturers' ballasts from a range of ELs and fixtures that span a range of applications for each equipment class. The BOMs describe the equipment in detail, including all manufacturing steps required to make and assemble each part. DOE then developed a cost model to convert the BOMs for each representative unit into manufacturer production costs (MPCs). By applying derived manufacturer markups to the MPCs, DOE calculated the MSPs [28] and constructed industry cost-efficiency curves. In cases where DOE was not able to generate a BOM for a given ballast, DOE estimated an MSP based on the relationship between teardown data and retail data. DOE also estimated ballast and fixture cost adders necessary to allow replacement of more-efficient substitutes for baseline models.

2. Representative Equipment Classes

As described in the previous section, DOE selects certain equipment classes as "representative" to focus its analysis. The 24 equipment classes (based on rated lamp wattage, indoor or outdoor designation, and test voltage) and the criteria used for development are presented in section V.A.2. Due to their low shipment volume (as indicated through manufacturer interviews), DOE does not directly analyze the equipment classes containing only fixtures with ballasts tested at 480 V. DOE selected all other equipment classes as representative, resulting in a total of 12 representative classes that cover the full range of lamp wattages, as well as indoor and outdoor designations. DOE had only analyzed 10 representative equipment classes in the NOPR. This increase is a result of DOE's decision to split the 501 W–2000 W equipment classes into 501 W–1000 W and 1001 W–2000 W. This new equipment class structure is discussed in section V.A.2.

3. Representative Wattages

In the NOPR, DOE selected five representative wattages of MHLFs (70 W, 150 W, 250 W, 400 W, and 1000 W) to analyze in the engineering analysis. Each representative wattage was typically the most commonly sold wattage within each equipment class, based on analysis of fixture availability from catalogs and manufacturer input.

As discussed in section V.A.2, DOE has split the 501 W–2000 W equipment classes from the NOPR into 501 W–1000 W and 1001 W–2000 W in the final rule. From 501 W–1000 W, DOE still finds 1000 W to be an appropriate representative wattage based on it being the most commonly sold. In the final rule, DOE is analyzing 1500 W as the representative wattage for the 1001 W–2000 W equipment classes based on this wattage being the most commonly shipped in the wattage range.

4. Representative Fixture Types

After selecting representative wattages for analysis, DOE identified the applications commonly served by each equipment class's wattage range in order to select representative fixture types. DOE recognizes that technological changes in the ballast caused by standards considered in this rulemaking, especially moving from magnetic ballasts to electronic ballasts, could necessitate alterations to the fixture. These changes often incur additional costs depending on the fixture type that needs to be altered. In the engineering analysis, DOE estimates a baseline fixture cost, as well as incremental costs to the fixture based on the type of ballast used (*e.g.*, electronic ballasts require specific fixture adaptations that magnetic ballasts do not). The cost adders to the fixtures are discussed in section V.C.12.

In the NOPR, DOE selected one to three representative fixture types for each rated wattage range based on the most common application(s) within that range. For the 50 W–100 W range, DOE selected canopy fixtures as the representative fixture types. For the 101 W–150 W and 150 W–250 W range, DOE selected canopy, low bay, and wallpack fixtures as representative fixture types. For wattages greater than 250 W, DOE chose canopy, flood, and high bay fixtures as representative fixture types.[29]

In this final rule, DOE has expanded its analysis of representative fixtures to account for separate uses in indoor and outdoor applications. This allows DOE to develop separate prices for indoor and outdoor fixtures, taking into account the weather protection built into outdoor fixtures. The new representative fixture types, which include from one to four applications for each equipment class, are shown in Table V.3.

TABLE V.3—REPRESENTATIVE WATTAGES AND FIXTURES

Designed to be operated with lamps of the following rated lamp wattage	Representative wattage	Representative fixture types	
		Indoor	Outdoor
≥50 W and ≤100 W	70 W	Recessed Can	Wallpack, Post Top, Flood.
>100 W and <150 W*	150 W	Low Bay	Parking Lot, Area, Wallpack, Flood.
≥150 W and ≤250 W**	250 W	Low Bay	Area, Flood, Wallpack.
>250 W and ≤500 W	400 W	Flood, High Bay	Pole Top, Flood.
>500 W and ≤1000 W	1000 W	High Bay	Flood, Sports.
>1000 W and ≤2000 W	1500 W	Sports	Sports.

*Includes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

[28] The MSP is the price at which the manufacturer can recover all production and non-production costs and earn a profit. Non-production costs include selling, general, and administration (SG&A) costs, the cost of R&D, and interest.

[29] Descriptions of each of these fixtures types can be found in chapter 3 of the final rule TSD.

** Excludes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

5. Ballast Efficiency Testing

After selecting representative wattages and fixture types, DOE purchased and tested MH ballasts, ranging from low-efficiency magnetic to high-efficiency electronic, in order to evaluate the range of commercially available ballast efficiencies. In selecting units for testing and analysis, DOE focused its effort on representative wattage ballasts with operating characteristics similar to ballasts most prevalent in the market. For example, through interviews and an assessment of commercially available MH ballasts, DOE learned that the majority of MH ballasts sold are quad-input voltage ballasts. Thus, DOE primarily tested MH ballasts capable of quad-input operation. Similarly, DOE found that at low wattages (less than or equal to 150 W), high-reactance autotransformer (HX) ballasts and CWA ballasts are most prevalent. At higher wattages, CWA ballasts compose the vast majority of the market. In consideration of these findings, DOE focused its testing and analysis on HX and CWA ballasts for the 70 W to 150 W range and CWA ballasts for all other wattage units.

DOE calculated average ballast efficiencies, across four samples, in accordance with MH ballast test procedures (10 CFR 431.324) by dividing measured output power by measured input power. As discussed in sections V.C.7 and V.C.8 of this notice, DOE selects baseline and higher-efficiency representative units for analysis based on these average efficiencies. Also, as discussed in the following section, DOE determines representative ballast input power for each EL based on these tested ballast efficiencies. To determine the ELs under consideration, as discussed in section V.C.9 of this notice, DOE uses a reported efficiency value based on the four tested samples, pursuant to the MH ballast certification procedures in 10 CFR 429.54.

6. Input Power Representations

As MH lamps age, they exhibit higher voltages, which can lead to higher system input power over the life of the lamp. Electronic ballasts have the capability to sense that the lamp voltage has increased and, in response, decrease their output current to maintain constant wattage throughout the life of the ballast. In the NOPR, DOE noted that magnetic ballasts do not have this capability and therefore the system wattage of magnetic MH ballasts would increase in response to an increase in lamp voltage over the lamp life. Therefore, DOE used a 5.5 percent increase in the NOPR when calculating the representative input power of magnetic ballasts.

Venture, NEMA, and ULT commented that while there is a voltage rise over the life of MH lamps, it can be extremely variable based on lamp design and manufacturing tolerances. Venture cautioned against applying a single factor to increase power across all ballasts. (Venture, Public Meeting Transcript, No. 48 at p. 178; NEMA, No. 56 at p. 15; ULT, No. 50 at pp. 8–9) ULT further asserted that DOE did not consider that ballast efficiency increases with a lamp's voltage and age, and also that many lamps have voltage below the nominal level when new. (ULT, No. 50 at pp. 8–9) In contrast, CA IOUs agreed with DOE on the increase in system input power and voltage that occurs over a ballast's life, but remarked that this increase may not be linear, and that the increase is smaller with electronic ballasts than with magnetic ballasts. They suggested that DOE continue to research this area, as the 5.5 percent figure determined could be an underestimation of the advantages of electronic ballasts. (CA IOUs, No. 54 at p. 7)

In the NOPR, DOE's inclusion of a 5.5 percent increase in input power for magnetic ballasts was based on feedback from manufacturers gathered during interviews. After reviewing the NOPR interview feedback in light of the new comments and conducting additional research on this topic, it was unclear whether the input power of magnetic ballasts actually increased over the ballasts' lifetime and, if it did increase, what the magnitude of that increase would be. Therefore, in this final rule DOE has not applied a scaling factor to increase the input power of magnetic ballasts.

7. Baseline Ballast Models

DOE selected baseline models as reference points for each representative equipment class, against which DOE measured changes in energy use and price resulting from potential amended energy conservation standards. For MHLFs and MH ballasts subject to existing federal energy conservation standards, a baseline model is a commercially available ballast that just meets existing standards and provides basic consumer utility. If no standard exists for a specific fixture type (*e.g.*, less than 150 W or greater than 500 W fixtures), DOE chooses baselines that represent the least efficient equipment (based on average tested ballast efficiencies) or highest-volume equipment within the representative parameters defined (*e.g.*, representative wattage, magnetic circuit type, input voltage).

For the NOPR, DOE analyzed a CWA, quad-input voltage, pulse-start baseline ballast for the 70 W, 150 W, 250 W, and 400 W representative wattages. As electronic ballasts comprise a significant portion of the 50 W–100 W ballasts shipped with indoor fixtures, for the 70 W representative wattage DOE analyzed a second baseline ballast utilizing an LFE circuit and operating at quad-voltage. For the 1000 W representative wattage, DOE analyzed a CWA, quad-input voltage, probe-start baseline ballast.

a. 70 W Baseline Ballast

In the NOPR, DOE analyzed an electronic ballast as a second baseline ballast for the 70 W representative wattage. DOE included this second baseline because it had determined that electronic ballasts comprise a significant portion (estimated as more than 25 percent) of the 50 W–100 W ballasts shipped with indoor fixtures. NEMA agreed with the addition of the electronic 70 W baseline ballast. (NEMA, No. 56 at p. 15) Receiving no comments in opposition, DOE has continued analyzing both an electronic and magnetic baseline ballast at 70 W for this final rule.

b. 1000 W Baseline Ballast

In the NOPR, DOE identified a probe-start ballast as the 1000 W baseline unit. While DOE acknowledged that pulse-start ballasts are available at the 1000 W level, it noted that probe-start, CWA, quad-voltage units are predominant in the high-wattage category, and are therefore the most appropriate baselines.

Musco Lighting questioned why a probe-start ballast was used as the 1000 W baseline ballast if this standard is suggesting a shift towards pulse-start in all equipment classes. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 130) As discussed previously, a baseline ballast is the most common, least efficient ballast at the representative wattage, without the imposition of standards (*i.e.*, the base case). The

baseline unit is meant to measure changes resulting from potential amended energy conservation standards compared with this baseline. DOE found that while pulse-start ballasts are available at the 1000 W level, probe-start ballasts currently dominate the market. As it is much more common for 1000 W ballasts to be probe-start, DOE continued to analyze a probe-start ballast as the 1000 W baseline unit in this final rule.

c. 1500 W Baseline Ballast

In the NOPR, a 1000 W baseline was analyzed in the 501 W to 2000 W equipment class. In this final rule, DOE divided this wattage range into a 501 W–1000 W equipment class and a 1001 W–2000 W equipment class (see section V.A.2 of this notice). DOE continued to analyze a 1000 W baseline in the 501 W to 1000 W equipment class. In the 1001 W–2000 W equipment class, DOE analyzed the 1500 W wattage as representative. Therefore, DOE added a baseline model at the new representative wattage, 1500 W, to represent the most common, least efficient ballast in the 1001 W–2000 W representative equipment class. The baseline unit for 1500 W is a magnetic CWA ballast and has a ballast efficiency of 92.9 percent.

d. Summary of Baseline Ballasts

In summary, after considering the comments received and changes to the equipment class structure, DOE has selected seven baseline units for analysis: 70 W magnetic, 70 W electronic, 150 W magnetic, 250 W magnetic, 400 W magnetic, 1000 W magnetic, and 1500 W magnetic.

8. Selection of More-Efficient Units

After the selection of baseline models, DOE used a combination of two methods to determine more-efficient units for analysis within each representative equipment class. The first method was examining DOE's own test data (discussed in section V.C.5 of this notice) to select commercially available ballasts to represent higher ELs. The second method involved filling in large gaps of efficiency present in the test data (often between commercially available magnetic and electronic ballasts) by modeling ballasts with improved efficiency due to the implementation of several of the design options described in section V.B of this notice. DOE derived those estimates based on manufacturer interviews and by validating or supplementing that feedback with independent modeling of potential reductions in ballast losses. Specifically, DOE used the watts loss per pound characteristics for various steel types to determine the levels of efficiency modeled ballasts could achieve.

DOE developed a max-tech magnetic ballast based on either commercially available equipment or a modeled ballast that utilized the highest grade steel practicable for manufacturing MH ballasts. For further details on the higher-efficiency units analyzed in this final rule, see chapter 5 of the final rule TSD.

a. Higher-Efficiency Magnetic Ballasts

DOE recognizes that several commercially available magnetic ballasts may already utilize the most efficient design options and have reached their efficiency limit. However, based on feedback from manufacturer interviews, DOE has learned that for each of the representative wattages analyzed, there exist design options to improve efficiency of magnetic ballasts. Therefore, DOE utilizes these design options to estimate the max-tech efficiency for magnetic ballasts for each representative wattage. DOE received a number of comments in response to the NOPR regarding the modeled higher-efficiency magnetic ballasts, specifically regarding the modeling method, performance characteristics of the modeled more-efficient units, and the impacts on fixture and ballast redesign.

Modeling Method

In modeling more-efficient magnetic ballasts for the NOPR, DOE maintained the physical size of the higher-efficiency models relative to commercially available magnetic ballasts within the representative wattages (*i.e.*, the modeled ballasts did not increase in size compared to what's currently available on the market). By using design information provided by manufacturers, DOE assumed improvements to the core steel and conductor of the commercially available magnetic ballasts to determine the higher-efficiency magnetic ballast efficiency and prices.

NEMA explained that core losses are determined by the type of material being used, the most efficient being M6 steel. Wire loss is generated from electrical resistance, and the most efficient wire material used is copper. (NEMA, No. 56 at p. 3) NEMA cited that for EL1 and EL2, the model assumes a higher quality steel will be used than is provided in the baseline unit. (NEMA, No. 56 at p. 10) NEMA and ULT noted that the EL2 calculation appears speculative, and that to move from EL1 to EL2 would require a 17 percent reduction (in the case of 70 W ballasts) in ballast losses, which is unfeasible. (NEMA, No. 56 at p. 10; ULT, No. 50 at pp. 6–7) NEMA commented that DOE underestimated both core steel losses and winding losses, which led to overestimates of feasible efficiencies. (NEMA, No. 56 at p. 11)

Regarding core losses, NEMA and ULT noted that the watts loss per pound of core steel constants DOE provided in the NOPR TSD are correct numbers obtained by an Epstein test [30] per the ASTM A–343 standard. However, NEMA and ULT stated that those numbers would be more appropriate to use for power transformers than for ballasts, and that the values are deceiving when applied directly to ballast core loss calculations. NEMA and ULT gave the example that M6 steel is shown to have 0.66 W/lb losses at 1.5 Tesla 60 Hz sine flux along the grain, when losses across the grain for M6 steel in an MH ballast are approximately 1.2 W/lb. Furthermore, NEMA and ULT explained that when ballast laminations are welded during manufacturing, grain-oriented material degrades substantially, and the losses increase. (NEMA, No. 56 at p. 11; ULT, No. 50 at p. 7) Philips agreed, commenting that the watts per pound loss for M6 steel would more than double during the manufacturing process, limiting the benefit of using this steel. (Philips, Public Meeting Transcript, No. 48 at p. 120) Philips also explained that the increase in M6 core losses is because welding disrupts the magnetic properties of the material. (Philips, Public Meeting Transcript, No. 48 at p. 121) Additionally, NEMA and ULT commented that magnetic flux in MH ballasts is not purely sinusoidal, rather it also includes harmonic frequencies that increase losses. They commented that even relative ratios of the losses provided in the NOPR TSD would not work, because data for grain-oriented steels are found using the 100 percent along the grain Epstein test, while data for cold-rolled steels, such as M19, use the 50 percent Epstein test. This 50/50 Epstein test takes into account and averages losses along the grain and across the grain. Therefore, DOE is not comparing equivalent measurements when simply using the already calculated core loss values presented in the NOPR. (NEMA, No. 56 at p. 11; ULT, No. 50 at p. 7)

In this final rule, DOE has revised its approach to modeling the efficiency of magnetic ballasts. The efficiency of

[30] An Epstein test is a method for evaluating a steel's magnetic properties by testing its performance with a standardized Epstein frame. During the measurement the Epstein frame, comprising a primary and a secondary winding, behaves as an unloaded transformer and the power losses are then measured with a wattmeter.

commercially available ballasts is established by independent test data conducted in accordance with the DOE test procedure, or taken directly from a manufacturer's ballast data sheet when test data was unavailable. Based on feedback obtained during individual manufacturer interviews, DOE assigned design characteristics to these commercially available ballasts. Design characteristics included core steel type, core mass, wire material, and wire mass. To analyze more-efficient ballast designs than those currently on the market, DOE calculated the change in efficiency (*i.e.*, change in ballast losses) resulting from a substitution of steel type.

Regarding the core loss calculations, DOE revised its loss values for M6 steel in response to the comments received. In the NOPR, the losses per pound values for M6 steel were based on alignment of the magnetic field longitudinally (in the same direction as the grain orientation) to the core steel. However, portions of the magnetic field are aligned transverse (perpendicular to the grain orientation) to the core steel. The core losses in the transverse orientation are much higher. For this final rule, DOE calculated a weighted average of longitudinal and transverse losses as the core loss factor for M6 steel and found that about one third of losses are in the transverse direction. Using this information, DOE calculated the average core losses, in W/lb, for M6 steel. See chapter 5 of the final rule TSD for additional detail. With this revision, the M6 loss value is comparable with the conventional cold-rolled steel (such as M19) 50/50 Epstein-test-based loss per pound values.

To calculate the losses associated with an EL2 ballast that uses M6 steel, DOE first calculated the losses of the EL1 ballast of the same wattage, by dividing lamp wattage by ballast efficiency, and then subtracting the lamp wattage. Next, DOE calculated the core losses of the EL1 ballast based on the mass of the EL1 core and the watts per pound loss value associated with the type of steel used in the EL1 ballast. Then, assuming the footprint and stack height cannot change, DOE assumed the EL2 M6 core would have the same mass. DOE therefore multiplied the M6 loss per pound value by the mass of the EL1 core to calculate the losses assuming an M6 steel substitution. DOE assumed all other losses remained constant, and therefore reduced the total EL1 ballast losses by the incremental decrease in core losses associated with the M6 steel. Regarding the 70 W ballasts, this final rule now models an increase in ballast efficiency from 76.6 percent to 78.4 percent, based on the decrease in core losses (and therefore increase in ballast efficiency) from M19 to M6 steel. This is a reduction in losses of 9.1 percent relative to EL1.

Regarding the resistive losses in the windings, NEMA and ULT stated that DOE's assumption that the current in the primary side of the transformer was approximately equal to the input current to the ballast is incorrect. This incorrect assumption would lead to calculated losses substantially lower than actual losses. (NEMA, No. 56 at p. 11; ULT, No. 50 at pp. 7–8) NEMA and ULT pointed out that the current in the secondary coil of the transformer does not need to be estimated, as it is equal to lamp current. (NEMA, No. 56 at p. 11; ULT, No. 50 at p. 8) NEMA and ULT suggested that as lamp current is responsible for winding losses, it should be used as a technical parameter when screening ballast design options. (NEMA, No. 56 at p. 10; ULT, No. 50 at p. 6)

DOE agrees with NEMA and ULT's description of current in various stages of the magnetic ballast. In an HX ballast, the presence of a capacitor in parallel with the primary transformer winding increases the current in the primary winding relative to the input current from the power source. With the secondary winding, the current is equal to the lamp current, which is given in ANSI C78.43–2010. However, for the final rule, modeled ELs are only based on substitution of electrical steel, assuming all else remains equal. Therefore, the comments relating to resistive losses based on current are not applicable to DOE's final rule calculations.

Modeled More-Efficient Units

In the NOPR, DOE used the modeling ballast methodology to calculate the efficiency of ballasts more efficient than those currently available for sale. NEMA, Philips, and ULT stated that 150 W fixtures could not meet the proposed efficiency requirement. (NEMA, Public Meeting Transcript, No. 48 at p. 33; Philips, Public Meeting Transcript, No. 48 at p. 48; ULT, No. 50 at pp. 23–24) ULT commented that an efficiency requirement for 150 W magnetic ballasts higher than currently commercially available equipment would practically ban 150 W magnetic autotransformer ballasts. (ULT, No. 50 at pp. 23–24) NEMA and ULT suggested that DOE made a mistake in considering how magnetic ballast efficiency behaves as a result of design considerations. As ballast wattage decreases, efficiency loss factors are compounded and the ballast size necessary to achieve potential efficiency gains increases, making it difficult to further raise the efficiency of ballasts 150 W and below. (NEMA, No. 56 at p. 3; ULT, No. 50 at pp. 19–24) ULT noted that typically, as lamp wattage decreases, so does lamp current. As 150 W lamps have higher lamp current than 175 W ballasts, it is more difficult for the 150 W ballasts to achieve high efficiencies. ULT noted that this relationship is the net effect of three main factors: (1) Higher current, (2) increased inductance, and (3) wire cross-section. In conjunction, these factors make it impossible to have an 88 percent efficient 150 W magnetic ballast on a 3x4 frame. Hence, the industry has not developed a 150 W MHLF with an 88 percent efficient magnetic autotransformer ballast in response to EISA 2007. (ULT, No. 50 at pp. 23–24) Furthermore, ULT stated that as ballasts ranging from 50 W to 150 W would need to increase in size in order to meet the EL proposed in the NOPR, these ballasts would not fit in the fixtures for which they were previously suitable. (ULT, No. 50 at p. 6) Philips clarified that the increase in size comes from the magnetic ballast stack height. Philips noted there are options for electronic ballasts, but they are not necessarily interchangeable and might be too big for existing fixtures. (Philips, Public Meeting Transcript, No. 48 at p. 50)

DOE notes that the level proposed at 150 W in the NOPR was intended to only be met by electronic ballasts, as are all EL3 and EL4 levels in both the NOPR and this final rule. DOE agrees with ULT that 150 W autotransformer ballasts cannot reach 88 percent efficiency with today's technology. In the NOPR, the magnetic ELs were set at 84.0 percent for EL1 and 86.5 percent for EL2. DOE disagrees that an EL above commercially available equipment would ban 150 W magnetic ballasts, as improving the core steel to M6, even while maintaining the same core footprint and weight, would improve the magnetic ballast efficiency beyond commercially available levels. DOE agrees that 150 W ballasts have a lower maximum achievable efficiency relative to 175 W ballasts, and has analyzed the 150 W fixture exempted by EISA 2007 accordingly. For this final rule, DOE revised the magnetic ballasts analyzed as more efficient replacements for the 150 W representative wattage. DOE selected a more common replacement ballast for EL1. At EL2, revisions in the magnetic ballast modeling resulted in changes to the performance characteristics. In the final rule, as in the NOPR, the ballast efficiencies analyzed at both EL1 and EL2 are less than 88 percent.

APPA and NEMA commented that the modeled magnetic ELs are not technologically feasible, as modeling and calculations are not proof of concept and do not account for variability in manufacturing. (APPA, No. 51 at pp. 7–8; NEMA, No. 56 at pp. 2, 24) NEMA and ULT also commented that the proposed characteristics of the modeled magnetic ballasts are based on theories, but have not been proven in manufacturing or physical testing and are therefore infeasible and cannot be tested for form, fit, or functions compatibility. ULT further asserted that the max-tech magnetic levels would require higher grade steel and wire, and would therefore increase ballast size. (NEMA, No. 56 at p. 11; ULT, No. 50 at pp. 4, 8, 30) In addressing the technological feasibility of the max-tech levels, NEMA stated that most max-tech levels selected for magnetic ballasts are possible only in laboratory conditions, and even then only with electronic ballasts. In cases where magnetic ballasts could reach the EL, they would need to be enlarged, and might not fit in existing fixtures. (NEMA, No. 56 at p. 10) Philips questioned whether a modeled product proves technological feasibility. (Philips, Public Meeting Transcript, No. 48 at p. 214) Philips also questioned whether interviews with manufacturers were enough to constitute an assessment of technological feasibility without actual proof. (Philips, Public Meeting Transcript, No. 48 at p. 215) NEMA stated that many other rulemakings select products of the highest efficiency that are already commercially available, as opposed to modeling something that has not been produced yet. Philips stated that it is unreasonable to think that there would not be other changes required in order to implement the modeled product. (Philips, Public Meeting Transcript, No. 48 at p. 221)

DOE conducted interviews with individual manufacturers for the NOPR analysis and received information through that process describing the design characteristics of ballasts more efficient than those currently in production. DOE then validated that information by calculating the incremental change in losses associated with substituting the electrical steel of a commercially available ballast for a higher grade of steel. While it is true that the ballasts directly analyzed at EL2 are not currently commercially available, the design option (M6 steel) used to create these ballasts is commercially available. M6 steel designs are used for 175 W ballasts with a 3x4 footprint, as evidenced by public comment during the preliminary analysis and NOPR phases of this rulemaking. In addition, DOE purchased and inspected a 175 W 3x4 magnetic ballast, and found the lamination thickness (0.14 inches) was indicative of M6 steel. DOE has modified its calculations of the benefits of M6 steel based on comment received from industry, but continues to analyze modeled ballasts for some ELs.

APPA and NEMA commented that meeting EL2, which DOE based on modeled magnetic ballasts, will actually require electronic ballasts. APPA and NEMA especially noted that the 91.5 percent efficiency requirement for 250 W ballasts is only achievable with electronic ballasts. (APPA, No. 51 at pp. 7–8; NEMA, No. 56 at pp. 2, 24) Overall, ULT stated that EL2 is too high for magnetic ballasts. (ULT, Public Meeting Transcript, No. 48 at p. 137) NEMA and ULT commented that the proposed efficiency standards would only be achievable by magnetic ballasts in some lab conditions, and would therefore require everything less than or equal to 750 W to be redesigned. (NEMA, Public Meeting Transcript, No. 48 at pp. 32, 37; NEMA, No. 56 at pp. 2, 10; NEMA, No. 44 at p. 9; ULT, No. 50 at pp. 2, 4, 10) Therefore, NEMA suggested that the max-tech magnetic levels (EL2) of this rule be lower than proposed. (NEMA, No. 56 at p. 12) However, the Joint Comment provided a listing of various magnetic ballasts capable of meeting the max tech magnetic levels (EL2), 13 of which exceeded both EL2 and EL3, and two exceeded EL4. (Joint Comment, No. 62 at p. 6) The Joint Comment noted that reactor ballasts represent a high-efficiency magnetic alternative to electronic ballasts for many applications and urged DOE to model these ballasts as the equipment chosen by customers in many cases when the standard is set at EL3 or EL4. (Joint Comment, No. 62 at p. 7)

DOE found that after revising its assumptions for M6 core losses, EL2 at 250 W (and other wattages) decreased relative to the NOPR. The 250 W EL2 is now set at 91.0 percent based on an M6 ballast design. DOE's analysis indicates both magnetic ballasts (using M6 steel) and electronic ballasts would be compliant with EL2 at 250 W. In response to the model list given by the Joint Comment, the commercially available magnetic ballasts that were noted as capable of meeting EL2 were single-voltage reactor ballasts. DOE agrees that there are commercially available reactor ballasts that have increased efficiency compared to more common magnetic ballast circuit types, but has chosen not to model them for EL3 and EL4. Reactor ballasts have limited utility due to their single input voltage and reduced ability to mitigate input voltage variation relative to HX or CWA ballasts, though these limited features do lead to increased efficiency. As discussed in section V.C.7 of this notice, DOE bases its analysis on CWA and HX magnetic ballasts. DOE has accounted for the thermal and voltage transient concerns with electronic ballasts with the design changes discussed in section V.C.8 of this notice.

Fixture and Ballast Redesign

DOE noted in the NOPR that its modeling method would not require changes in ballast or fixture size relative to those currently commercially available. NEMA, ULT, and GE commented that DOE's assumption that proposed ELs will not require changes to the size of the ballast is incorrect, especially for ballasts in the 50 W–150 W range, noting that the fixtures would need to be replaced to reach those levels. (NEMA, No. 56 at p. 14; ULT, No. 50 at p. 6; GE, Public Meeting Transcript, No. 48 at p. 190) ULT stated that as the ballast size would increase, the proposed financial analysis, and market and manufacturer impact, might be incorrect. (ULT, Public Meeting Transcript, No. 48 at p. 66) ULT asked how DOE could be sure that ballast size would not increase if in some cases ballasts meeting the max tech magnetic ELs were not yet commercially available. (ULT, Public Meeting Transcript, No. 48 at p. 140) Similarly, NEMA requested that DOE explain its assumption that there will be no size increase. (NEMA, No. 56 at p. 14) However, CA IOUs and the Joint Comment supported DOE's modeled teardown approach as an indicator of potential higher-efficiency equipment that could be manufactured in the future, and an indicator that the max tech magnetic standard levels would not necessarily increase ballast size. (CA IOUs, No. 54 at p. 2; Joint Comment, No. 62 at p. 6)

As discussed previously, DOE's modeling approach for magnetic ballasts does not change the ballast footprint or stack height relative to a commercially available ballast. For example, when modeling an EL2 magnetic ballast, all parameters remain constant except for a substitution of the electrical steel. The cost and efficiency associated with the DOE's magnetic ballast analysis is based on the constraint that ballast size (footprint and stack height) is not allowed to change. As discussed in section V.I of this notice, DOE notes that any modifications to fixtures necessary so that the fixture can be used in

conjunction with electronic ballasts can be completed during the manufacturing process, and the costs associated with these new processes are accounted for in the MIA. This regulation does not require retrofitting of MHLFs already installed in the field.

CA IOUs also illustrated the existence of high efficiency magnetic ballasts throughout the wattage ranges, which conflicts with manufacturer claims that ELs beyond EL1 could not be achieved by magnetic ballasts. (CA IOUs, No. 54 at pp. 3–7) DOE notes that the ballasts found with higher than EL1 efficiencies in the CEC database were either reactor ballasts or ballasts capable of only one input voltage. As discussed in section V.C.7, DOE only identified ballasts that were quad-voltage and either CWA or HX as representative. While there are more efficient ballasts, if DOE were to set an EL that only permitted single input voltage or reactor ballasts then there would be significant utility lost.

NEMA and ASAP cautioned that any standard requiring a larger ballast for one wattage will likely require a larger ballast to be designed for all wattages within the associated range. This will increase the ballast size, weight, and the cost of materials (steel and aluminum) for a broad range of equipment—not just the wattage directly analyzed. (NEMA, No. 56 at p. 14; ASAP, Public Meeting Transcript, No. 48 at p. 63) For example, ULT commented that coverage of the 50 W–100 W range would require redesign of all magnetic ballasts of that range. EEI and Acuity commented that increasing the size of a ballast would require increasing the size of the accompanying fixture, which would use more natural resources and would impact wind-loading requirements. (EEI, Public Meeting Transcript, No. 48 at p. 59; Acuity, Public Meeting Transcript, No. 48 at p. 59) ULT further affirmed that bigger ballasts would lead to alterations of fixture housing, and thus to a complicated replacement process affecting the entire installed base. Replacing all the MHLFs currently installed, especially in applications, such as light poles, where more than the fixture would have to change to accommodate the mounting of a larger ballast, would have a negative impact on the whole market. (ULT, Public Meeting Transcript, No. 48 at p. 61) APPA noted that altered design specifications and wind-loading requirements are significant cost adders. (APPA, Public Meeting Transcript, No. 48 at p. 62)

As stated previously, DOE does not analyze a level that would require an increase in ballast size relative to commercially available ballasts. All magnetic ballasts are either commercially available, or modeled using the size constraints of a commercially available ballast. All electronic ballasts analyzed are commercially available. Thus, DOE does not find that the ballast efficiencies analyzed in this final rule would necessitate an increase in ballast size. Regarding ballast weight, electronic ballasts tend to be lighter than magnetic ballasts. For fixtures, DOE analyzed the size of fixtures on pole tops (parking/area fixtures and acorn-style post tops) to determine if any ELs would increase the surface area of fixtures to the point of causing concerns with wind loading. DOE found no evidence that fixtures listed for only magnetic ballasts, versus those listed for both electronic and magnetic or only electronic had a systematically different wind resistance (effective projected area—surface area of the largest side) or overall weight. Thus, DOE does not find that the ballast efficiencies analyzed in this final rule would necessitate an increase in fixture size.

GE commented that manufacturers could choose to rate ballasts conservatively (i.e., overdesign the ballast) compared to standards, thus providing a cushion between the regulation and the ballasts' tested efficiency. This approach would translate into increased size and material costs. (GE, Public Meeting Transcript, No. 48 at p. 89)

DOE acknowledges that manufacturers have flexibility in choosing how to design and rate their products. However, DOE does not require manufacturers to rate a product at a certain increment above the adopted standard level. Therefore, DOE has not accounted for any increase in ballast size or material cost that may result from such a decision.

b. Electronic Ballasts

In the NOPR, DOE analyzed electronic ballasts as higher-efficiency replacements for magnetic ballasts and based max-tech efficiencies for 50 W to 500 W MHLFs on commercially available electronic ballasts independently tested by DOE. In response to that approach, DOE received several comments, discussed below, regarding outdoor transient protection, thermal protection, fixture and ballast redesign, electronic ballast applications, HFE ballasts, lumen maintenance, and other issues.

Transient Protection

In the NOPR, DOE recognized the necessity for outdoor fixtures to be able to withstand large voltage transients, primarily due to lightning strikes. While MHLFs with magnetic ballasts are robust and do not require any additional devices or enhancements to withstand these transients, based on its evaluation of commercially available MHLFs, DOE found that fixtures with electronic ballasts usually require additional design features in order to have adequate protection. Some manufacturers indicated that a portion of their electronic ballasts already have 10 kV surge protection built in, but most electronic ballasts are only rated for 2.5 kV–6 kV voltage spikes. Though magnetic ballasts are known to provide protection in excess of the 10 kV specified by the ANSI C62.41.1–2002 Class C rating, for the NOPR DOE only considered the cost of meeting the 10 kV requirement.

NEMA asserted the proposed efficiency standards would lead to a shift from magnetic to electronically ballasted fixtures that are more susceptible to transient surges. (NEMA, No. 56 at pp. 5–6; NEMA, No. 44 at p. 9; NEMA, Public Meeting Transcript, No. 48 at pp. 32–33) The South Carolina Electric and Gas Company (SCE&G), APPA, NEMA, and ULT noted that the need for additional surge protection in outdoor applications using electronic ballasts is real, as they will not handle transient surges as well as magnetic ballasts. (SCE&G, No. 49 at p. 1; APPA, No. 51 at p. 5; NEMA, No. 56 at p. 16; ULT, No. 50 at pp. 9–10) Acuity expressed concern that the efficiency standards could preclude necessary fixtures used in environments with transient voltage. (Acuity, Public Meeting Transcript, No. 48 at p. 162) SCE&G explained that magnetic ballasts contain larger coils and steel cores that better absorb energy. SCE&G added that the more robust protection required for electronic ballasts would add cost and complexity. (SCE&G, No. 49 at p. 1) Specifically, APPA and NEMA stated that transient surge protection would require a much larger front end or an external sacrificial device, resulting in additional reengineering cost. (APPA, No. 51 at p. 6; NEMA, No. 56 at p. 2)

DOE agrees that electronic ballasts need additional surge protection in outdoor applications. In this final rule, DOE continues to find that by providing external surge protection up to the 10 kV requirement of ANSI C62.41.1–200, electronic ballasts can be used in the same outdoor locations as magnetic ballasts. The cost of the additional equipment in outdoor applications is added to the total fixture MSP (see section V.C.12.c). Using electronic ballasts outdoors may also result in increased maintenance or replacement

costs for the voltage surge protection devices. These costs are accounted for in the LCC analysis (section V.F of this notice).

APPA, NEMA, and ULT noted that while it is not difficult to add extra surge protection, it is impossible to predict when the protection device will need to be replaced and how many strikes any given surge protector can handle over its lifetime before the ballast and lamp are affected. APPA, NEMA, and ULT added that voltage transients can be variable in severity and timeframe. The current requirements for surge protection only cover 10 kV, even though surges of 20 kV are common. ULT stated that even with transient protection, electronic ballasts would likely not withstand voltage transients as well as magnetic ballasts do. When the surge protector has reached the end of its life, the next surge will cause the ballast to fail. (APPA, No. 51 at pp. 5, 6; NEMA, No. 56 at pp. 2, 16; ULT, No. 50 at pp. 12–13. 16). SCE&G further commented that resources will be consumed while installing and repairing fixtures with electronic ballasts damaged by lightning. (SCE&G, No. 49 at p. 1) The Joint Comment agreed that the surge protection device might need to be replaced during a fixture's lifetime for some fixtures and this additional maintenance and repair cost should be analyzed by DOE. (Joint Comment, No. 62 at p. 5)

DOE has included the cost of transient protection capable of surge protection up to 10 kV in its estimates of the initial cost of outdoor MHLFs with electronic ballasts, as that is the level specified in ANSI C136.2–2004. DOE agrees that one difficulty arising from the addition of transient protection to electronic ballasts in voltage transient affected areas is the uncertainty in how many strikes the protection will be able to absorb and when the protective device will be sacrificed and the ballast made vulnerable. This vulnerability will affect the maintenance costs and average lifetime of outdoor electronic ballasts. See section V.F of this notice for discussion of these costs.

APPA suggested that DOE take into account data regarding the frequency and severity of lightning strikes in the United States and revise the forecasts for maintenance costs given the frequency and effect of strikes. A lightning strike can affect fixtures within a square kilometer, and according to National Lightning Safety Institute data, which would affect hundreds of ballasts each year. (APPA, No. 51 at p. 6) APPA and NEMA noted that besides lightning, there could be many other causes of transient surges, such as wind, transmission line movement, wind generator surges, equipment or load switching, and collapse of sections of a distribution network. (APPA, No. 51 at p. 6; NEMA, No. 56 at p. 17) APPA and NEMA urged DOE not to eliminate the desirable performance characteristics of magnetic ballasts from the market. APPA and NEMA predicted that replacement rates for outdoor fixtures would increase significantly for utilities and could cause safety and security concerns. (APPA, No. 51 at p. 6; NEMA, No. 56 at p. 16) Therefore, APPA and NEMA stated that the many causes of transient surges make magnetic ballasts necessary in outdoor applications. (APPA, No. 51 at p. 6; NEMA, No. 56 at p. 17)

As discussed previously, DOE has determined that electronic ballasts can be used as substitutes for magnetic ballasts when the necessary design changes are included. DOE agrees that transient protection is a critical consideration, which is why DOE is modeling electronically ballasted fixtures sold with transient protection devices, and also including transient protection device and ballast replacement costs. See section V.F of this notice for details on how DOE models the frequency with which outdoor ballasts encounter surges, and how those translate directly to increased maintenance and replacement costs, and the cost-effectiveness of these measures.

NEMA and ULT noted that indoor applications also expose ballasts to high voltage transients. While transient protection is needed to protect against lighting strikes in any outdoor application, it is also needed in heavy industrial indoor applications where large machinery can send massive transients across the power lines when they are turned on. (NEMA, No. 56 at p. 16; ULT, No. 50 at pp. 9–10)

In researching transient protection for the final rule, DOE found that indoor industrial fixtures are also subject to voltage surges. DOE has thus included voltage transient protection in its price analysis for indoor electronic ballasts experiencing transient surges in these industrial applications. Specifically, DOE analyzes the indoor industrial applications that require additional surge protection as an LCC subgroup. DOE found that indoor industrial MHLFs could experience voltage surges up to 6 kV. The voltage transient protection device used in DOE's analysis can withstand 120 surges of 3 kV, 18 surges of 6 kV, or 5 surges of 10 kV before failure. LCC subgroups are discussed in section V.H and the results of the subgroup analysis are presented in section VII.B.1.b.

Thermal Protection

In the NOPR, DOE found that fixtures with electronic ballasts had to be designed to tolerate electronic ballasts' higher sensitivity to temperatures. Manufacturers must design new and often larger brackets, and apply additional potting material, for example, to create an adequate thermal contact between the ballast and fixture housing. Based on manufacturer feedback and fixture teardown costs, DOE found that there was an approximately 20 percent increase in fixture MPCs to include thermal management for electronic ballasts.

Several stakeholders commented on the heat sensitivity of electronic ballasts. SCE&G stated that the most serious flaw of the electronic MH ballast concept is heat dissipation. The heat sensitivity of electronic ballasts would lead to a larger fixture, so that the fixture could achieve proper thermal management, adding cost and using more resources. (SCE&G, No. 49 at p. 1) One issue identified by stakeholders regarding the thermal management of electronic ballasts is that electronic ballasts cannot operate in the same temperature environments as magnetic ballasts. SCE&G, APPA, and NEMA stated that most electronic ballasts have an 80 °C internal operating temperature (or case temperature) limit, while their magnetic counterparts are in the greater than 180 °C range. (SCE&G, No. 49 at p. 1; APPA, No. 51 at p. 5; NEMA, No. 56 at pp. 5–6; NEMA, No. 44 at p. 9; NEMA, Public Meeting Transcript, No. 48 at pp. 32–33) ULT commented that this case temperature limitation results in the unavailability of electronic ballasts rated for operation in ambient air with a temperature higher than 50 °C. (ULT, No. 50 at pp. 2, 8–10) APPA and NEMA stated that this poses significant maintenance and operations issues for existing fixtures. In some cases, protecting against temperature sensitivity would require a utility to move from ballast replacement to entire fixture replacement. (APPA, No. 51 at pp. 5, 8; NEMA, No. 56 at pp. 2, 16, 24) Acuity expressed concern for high wattage fixtures used in extreme applications, stating that the efficiency standards could preclude necessary fixtures from being available for use in environments with high temperatures. (Acuity, Public Meeting Transcript, No. 48 at p. 162)

In addition, several stakeholders noted that the design of existing fixtures may create high temperature environments within the fixture itself,

which would be unsuitable for electronic ballasts. Philips commented that many MHLFs are designed with the core and coil of the ballast directly above the lamp, which creates a high temperature environment in which electronic ballasts cannot survive. (Philips, Public Meeting Transcript, No. 48 at p. 188) In addition, Philips stated that with higher system input power, there are often higher temperature environments, and it is difficult to find components, especially capacitors, rated at those high temperatures. (Philips, Public Meeting Transcript, No. 48 at pp. 194–195) GE questioned whether the EL models took into account thermal conditions and luminaire design, or if it just assumed the boundary conditions would match the ballast. GE ultimately agreed that DOE's model does not include the thermal characteristics of the fixture or the boundary conditions. (GE, Public Meeting Transcript, No. 48 at pp. 147, 217)

DOE agrees that thermal protection is required to render electronic ballasts suitable substitutes for magnetic ballasts in all applications. DOE accounts for this cost in section V.C.12 of this final rule. DOE also analyzed the commercially available fixtures that are advertised for use with electronic ballasts in outdoor locations. In extreme heat conditions, DOE has determined that electronic ballasts typically operate up to case temperatures of 80–90 °C. While magnetic ballasts themselves are able to handle temperatures as extreme as 180 °C, a magnetic ballast must be paired with a capacitor and DOE has determined that the capacitor typically only carries a temperature rating of about 100 °C. Furthermore, pulse start magnetic ballasts must be paired with an igniter in addition to a capacitor and DOE has determined that the igniter also typically carries a temperature rating of about 100 °C. Based on manufacturer interviews and assessment of commercially available fixtures, DOE believes that thermal design changes, such as new brackets or additional potting material to create an adequate thermal contact between the ballast and fixture housing, can address this 10–20 °C difference in temperature rating between electronic and magnetic ballasts. Therefore in this final rule, as in the NOPR, DOE has included a 20 percent increase in fixture MPCs to account for increased thermal management for electronic ballasts.

DOE acknowledges that existing fixtures designed for magnetic ballasts may not be suitable for electronic ballasts due to the need for increased thermal management. This rulemaking does not require retrofits of fixtures currently installed in the field. Any modifications to fixture design would be completed by the fixture manufacturer and incorporated in any new fixture sales. Fixture manufacturers already sell fixtures rated for use with electronic ballasts.

Fixture and Ballast Redesign

When analyzing electronic ballast levels (EL3 and EL4) in the NOPR, DOE assumed that the main design changes required to allow electronic ballasts were to increase thermal management, add voltage transient suppression, and add 120 V auxiliary power functionality. The costs of these design changes are discussed in section V.C.12 of this notice. In addition to the increased costs associated with these design changes, DOE also accounted for manufacturer conversion costs in the MIA.

ASAP agreed with DOE's methodology in analyzing the challenges and costs associated with using electronic ballasts in outdoor applications. (ASAP, Public Meeting Transcript, No. 48 at pp. 57, 62) CA IOUs and the Joint Comment stated that major manufacturers already offer electronic ballasts designed to be used outdoors. Further, electronic ballasts generate less internal heat and already make up approximately 25 percent of sales for some wattage bins. In addition, using the CEC compliance database, CA IOUs illustrated the high efficiency and availability of electronic ballasts for indoor and outdoor applications. (CA IOUs, No. 54 at pp. 3–7; CA IOUs, Public Meeting Transcript, No. 48 at p. 202; Joint Comment, No. 62 at pp. 4–5)

DOE also received several comments that questioned the feasibility of using electronic ballasts in all applications, in particular how requiring electronic ballasts could impact the need for ballast and fixture redesign. ULT stated that there is a difference between commercially available LFE ballasts and commercially available MHLFs effectively incorporating such ballasts. (ULT, Public Meeting Transcript, No. 48 at p. 204) APPA, the National Rural Electric Cooperative Association (NRECA), ULT, and EEI stated that magnetic ballasts are better suited to withstand temperature and transient extremes, wet locations, heat from the lamp, and would require larger fixtures. Therefore, the switch to electronic ballasts would require new designs, retooling, and cause a lack of replacements for existing fixtures. (APPA, No. 51 at p. 4; NRECA, No. 61 at p. 2; ULT, No. 50 at p. 2; EEI, No. 53 at p. 3) NEMA commented further that electronic ballasts for outdoor applications would need to be redesigned, and hardened and sealed, and thus made larger. (NEMA, No. 56 at p. 6) While California has regulations that require electronic ballasts in certain situations, NEMA pointed out that efficiency standards in California are low enough that the amount of redesign was not as challenging as it would be for some of the levels presented in the NOPR. (NEMA, Public Meeting Transcript, No. 48 at p. 199)

Stakeholders further stated that, because of the increased size of electronic ballasts and fixtures, there would be significant impacts on existing fixtures. APPA, NRECA, ULT, and EEI commented that the switch to electronic ballasts would require new designs, retooling, and cause a lack of replacements for existing fixtures. (APPA, No. 51 at p. 4; NRECA, No. 61 at p. 2; ULT, No. 50 at p. 2; EEI, No. 53 at p. 3) EEI elaborated, stating that electronic ballasts used for outdoor fixtures are larger and heavier than magnetic ballasts, which would make it harder to replace ballasts in existing fixtures. (EEI, No. 53 at p. 3) GE asserted that switching to electronic ballasts, especially outdoors, would take a great deal of care, attention, design, and development because it is not possible to put an electronic ballast into an existing magnetic fixture. (GE, Public Meeting Transcript, No. 48 at p. 198) APPA expressed concern regarding the ability to maintain existing infrastructure and Cooper Lighting (Cooper) cautioned against replacement fixtures not matching installations. (APPA, Public Meeting Transcript, No. 48 at p. 196; Cooper, Public Meeting Transcript, No. 48 at p. 71) In addition, Cooper commented that lighting fixtures are usually UL listed with a certain type of ballast and have fit and thermal issues among different suppliers. (Cooper, Public Meeting Transcript, No. 48 at p. 74) NEMA asserted the proposed efficiency standards would force a shift from magnetic to larger electronic ballasts that would not be interchangeable in fixtures. (NEMA, No. 56 at pp. 5–6; NEMA, No. 44 at p. 9; NEMA, Public Meeting Transcript, No. 48 at pp. 32–33)

DOE agrees that there would need to be adjustments made to the MHLF system to allow electronic ballasts to be used outdoors. DOE determined that electronic ballasts are capable of use outdoors by adding transient protection, thermal protection, and using fixtures specifically designed to be used outdoors. Outdoor fixtures that use electronic ballasts already exist in the marketplace and DOE research did not indicate any trend of these fixtures

being larger than comparable magnetic fixtures for the same wattage products. Furthermore, as discussed in section V.C.12, DOE revised its methodology for determining fixture pricing to ensure that the costs for outdoor fixtures housing electronic ballasts also incorporate the necessary weatherization.

DOE contends that the levels analyzed in this rulemaking will not require increases in ballast size. All magnetic ballast levels are designed to be achievable with magnetic ballasts commercially available or using magnetic ballasts that are the same size as commercially available ballasts. When switching to electronic ballasts, DOE notes that the sizes and shapes of electronic ballasts are typically different from magnetic ballasts (longer length but narrower width), but do not increase to a size that would cause concern about their use in any applications where magnetic ballasts are used. Any fixture redesign that is required to ensure fixtures comply with adopted standards was taken into account in the economic analyses of the final rule. As discussed above, DOE acknowledges that the surge protection device might need to be replaced during the fixture's lifetime and this maintenance cost, as well as potential early replacement costs from the surge protection being sacrificed and the next strike compromising the electronic ballast, are taken into account in the LCC analysis (section V.F of this final rule).

DOE has determined that replacement fixtures should have no issues with the adopted standard, as the size and weight of fixtures do not need to increase for any of the levels. While certain fixtures may require redesign for new ballast types, such as electronic, the overall size and weight of fixtures does not increase. DOE agrees that certain fixtures are UL listed and have compatibility assured with specific types of ballasts—but the ballasts affected by this rulemaking are those being placed in new fixtures and not those being used as replacements in existing fixtures. Any new fixture sold will be able to be cleared for UL listing and compatibility with the ballast included in the final assembly.

Regarding the most efficient levels analyzed, which require electronic ballasts, Philips stated that LFE MH ballasts cannot be made more efficient than the equipment already available. (Philips, Public Meeting Transcript, No. 48 at p. 70) DOE agrees that the efficiency of low frequency ballasts cannot be improved beyond that of currently commercially available ballasts. DOE's max tech electronic level (EL4) is based on commercially available low frequency ballasts.

In summary, in this final rule, DOE continues to model the cost of switching from magnetic ballasts to electronic ballasts, accounting for thermal management, transient protection, and general weatherization of the fixture in applications in which it is required.

Applications

Because DOE concluded that electronic ballasts and magnetic ballasts could provide the same utility in the wattages that electronic ballasts are offered (50 W to 500 W), DOE concluded in the NOPR that there was no application unique to magnetic or electronic ballasts. With the proper adjustments to the fixture, electronic ballasts could be used anywhere magnetic ballasts are used.

Several manufacturers commented on the prevalence of commercially available MHLFs listed for use with electronic ballasts. Cooper commented that they only use electronic ballasts in select MHLFs, including a very limited number of low-wattage fixtures in some garage applications. (Cooper, Public Meeting Transcript, No. 48 at p. 191) GE stated that they carry a 400 W electronic ballast, but it is used in retail applications with ideal operating conditions. (GE, Public Meeting Transcript, No. 48 at p. 191) Philips, on the other hand, commented that they make a lot of electronic MH ballasts, anywhere from 25 W to 400 W, mostly used in retail applications. However, these ballasts are primarily for use with CMH lamps and would not be suitable in existing fixtures, regardless of lamp type, without significant redesign. Philips added that there are no components available for applications greater than 400 W and the costs are approximately three times higher than magnetic ballasts (Philips, Public Meeting Transcript, No. 48 at pp. 192–193, 195) Acuity commented that the only applications with which they use electronic ballasts and low-wattage fixtures are downlights, cylindrical architectural lighting, and spaces meant for low-wattage fixtures where there is good power quality and no extreme temperatures. (Acuity, Public Meeting Transcript, No. 48 at p. 192) CA IOUs clarified that as this ruling applies to new fixtures only, they do not see a problem with electronic ballasts being used outdoors. (CA IOUs, Public Meeting Transcript, No. 48 at p. 196)

DOE identified fixtures for sale with electronic ballasts that were advertised for and intended for use in outdoor applications, such as exterior post top, outdoor area, bollard, canopy, security, and wall pack lighting. Manufacturers selling these fixtures did not provide any indication that they were to be used in a more limited set of applications relative to magnetic ballasts and did not contain warnings with regard to particular conditions that should be avoided when using those fixtures. For the previously described reasons, DOE has found that electronic ballasts can be used in outdoor applications assuming the proper adjustments have been made to the fixtures. Any overall fixture redesign or conversion costs incurred by the manufacturer to switch production to fixtures meeting these levels are accounted for in the MIA (see section V.I.4). DOE emphasizes that this rulemaking only applies to new fixtures.

High-Frequency Electronic Ballasts

In the NOPR, DOE analyzed HFE ballasts and determined that they were a valid design option to improve ballast efficiency. DOE acknowledged the lack of compatibility with CMH lamps, but proposed to take those impacts into account when adopting any amended standards.

NEMA commented that in the 320 W–400 W range, when developing electronic ballasts the industry is split between low-frequency square wave and high-frequency. (NEMA, Public Meeting Transcript, No. 48 at p. 28) However, NEMA warned that HFE ballasts are not compatible with all MH lamps; the size of the arc tube could lead to acoustic resonance problems, which cause arc instability and possible rupture of the arc tube. This would lead to compatibility problems where a ballast or lamp could not be readily replaced. (NEMA, Public Meeting Transcript, No. 48 at p. 28) NEMA expressed concern that there would likely be very limited lamp models that could be used with these high-efficiency, high-frequency ballasts. (NEMA, Public Meeting Transcript, No. 48 at p. 29; NEMA, No. 56 at p. 15) ULT agreed, commenting that there are applications where an electronic ballast will not work and an HFE-only standard would therefore be a mistake. (ULT, No. 50 at p. 8)

DOE agrees that there are compatibility issues with HFE ballasts and CMH lamps and that there are no industry standards in place for HFE ballasts. As discussed in section III.A.4, DOE has decided to not consider standards for HFE ballasts in this rulemaking. Given that HFE ballasts are no longer in the scope of the final rule, DOE revised the 400 W EL4 representative unit to be an LFE ballast. The final rule only analyzes LFE ballasts as representative units.

Lumen Maintenance

When analyzing the potential energy savings of electronic ballasts in the NOPR, DOE only considered the savings that would come from increased ballast efficiency. It was assumed that increased ballast efficiency when using the same wattage electronic MH system would still provide an equivalent light output.

The Joint Comment expressed its belief that DOE has significantly underestimated the energy and economic savings from electronic ballasts because lamps driven by electronic ballasts experience better lumen maintenance, which allows for fewer fixtures or lower-wattage lamps and less frequent re-lamping. (Joint Comment, No. 62 at pp. 1–2) The Joint Comment cited the following sources in support of the positive impact electronic ballasts have on lumen maintenance: (1) Natural Resources Canada stated an electronic ballast produced 15 percent more light output after 8000 hours; (2) GE claimed their UltraMaxTM electronic ballast produced 13 percent higher mean lumens at 40 percent of rated life than an MH system using a pulse-start magnetic ballast; (3) Advance claimed that their DynaVision® electronic ballast delivered a 20 percent improvement in lumen maintenance at 40 percent of rated life over a pulse-start MH system; and (4) Holophane claimed that electronic ballast technology increased mean lumen output by 13 percent on pulse-start lamps and stated that improved lumen maintenance is the most fundamental benefit of electronic HID ballasts. (Joint Comment, No. 62 at p. 2)

DOE researched the potential increase in lumen maintenance when switching from magnetic to electronic ballasts. While the comments cited several different examples of systems whose lumen maintenance was increased with electronic ballasts, DOE did not find universal agreement across the industry regarding the impact of electronic ballasts on lumen maintenance. While there seemed to be general agreement that electronic ballasts may have increased lumen maintenance, the literature indicated that specific claims may be unique to certain combinations of lamps and ballasts. There is no assurance that customers would choose an electronic ballast or lamp that would increase lumen maintenance if DOE adopted an electronic ballast standard level. As such, DOE maintains the approach from the NOPR to only consider the energy savings from increased ballast efficiency.

Additional Considerations

NEMA stated that mandating ELs that preclude any technology but pulse-start electronically ballasted MHLFs would cause increased maintenance and material costs due to surge and lightning resistance, increased fixture size and price, added weather resistance, remote igniter installation, and the higher maintenance cost and considerations of high-mast lighting fixtures. (NEMA, No. 56 at p. 8) APPA and Florida Power and Light were skeptical about electronic ballasts being able to withstand all types of outdoor threats, such as extreme cold, extreme heat, humidity, salt water, salt air, surge, sag, and swell. (APPA, Public Meeting Transcript, No. 48 at p. 196; Florida Power and Light, Public Meeting Transcript, No. 48 at p. 204) NEMA stated that electronic ballasts would require added capabilities of weather resistance, surge resistance, and thermal resilience. (NEMA, Public Meeting Transcript, No. 48 at p. 70)

DOE has accounted for the additional costs at any level requiring the use of electronic ballasts. DOE also agrees that electronic ballasts used outdoors require general weatherization. To account for this, DOE conducted additional fixture teardowns for this final rule to come up with a fixture price at each representative wattage that was unique for indoor versus outdoor applications. This way the outdoor fixtures incorporating electronic ballasts will account for the necessary weatherization. Weather resistance, voltage transient protection, and thermal protection are incorporated into the full fixture MSPs (see section V.C.12). Any potential redesign required of manufacturers is considered in the MIA (see section V.I.4). Maintenance is considered in the LCC analysis (see section V.F). DOE investigated whether a standard that requires an electronic ballast would negatively impact high-mast lighting applications using remote ballast placement. Some electronic ballasts are capable of starting lamps up to 33 feet, but magnetic ballasts can perform remote starting and lamp operation from longer distances. Unlike magnetic pulse-start ballasts, the ballast to lamp distance cannot be increased with a remote igniter, because this remote igniter device is not available for use with electronic ballasts. DOE investigated high-mast applications and determined some roadway applications with 30 to 40 foot poles could be utilizing the remote starting feature. It is unclear what percentage, if any, of the 30 to 40 foot poles use remote ballast placement, such that the remote starting ability of electronic ballasts would be an issue. Further, DOE notes that electronic ballasts are capable of starting lamps at distances exceeding 30 feet. The other main category of high-mast applications includes those at extreme heights, at least 100 feet, typical of sports stadium or airfield lighting. These applications require fixtures of 1000 W or higher. Because DOE is not analyzing efficiency levels that would require electronic ballasts at these high wattages, these high-mast, high-wattage MHLFs do not pose a concern. In summary, DOE concluded the need for remote starting does not necessitate the usage of magnetic ballasts.

Florida Power and Light commented that electronic ballasts are designed to work on a National Electrical Safety Code (NESC) three-wire system. However, Florida Power and Light runs a NESC two-wire system and is having difficulties with electronic drivers. Florida Power and Light stated that they have heard of similar issues from other utilities, such as Duke Energy and National Grid, and are very concerned about being forced into using electronic ballasts. (Florida Power and Light, Public Meeting Transcript, No. 48 at p. 204) DOE reviewed manufacturer literature for a variety of electronic ballasts and found no requirements that they be used in conjunction with a specific wiring scheme. The literature does stipulate that the electronic ballast should be grounded to earth, but does not speak to preferred or required wiring systems. DOE continued to analyze electronic ballasts in outdoor locations for this final rule.

9. Efficiency Levels

Based on the higher-efficiency ballasts selected for analysis, discussed in section V.C.8, DOE developed ELs for the representative equipment classes. EL1 represented a moderately higher-efficiency magnetic ballast, and EL2 represented the max-tech magnetic ballast. EL1 and EL2 were characterized by a combination of commercially available and modeled magnetic ballasts. EL3 represented the least efficient commercially available electronic ballast, and EL4 represented the max-tech level for all ballasts incorporated into MHLFs. In the NOPR, DOE created four ELs for the equipment classes with the 70 W, 150 W, 250 W, and 400 W representative wattages. Due to the fact that DOE did not analyze electronic ballasts for the 1000 W representative wattage, DOE analyzed only two ELs in the equipment class above 500 W.

NEMA and ULT offered revised efficiency equations, suggesting efficiencies lower than the NOPR

proposed levels. The levels are set with linear equations from 50 to 150 W and 500 to 1000 W, with a flat efficiency of 88 percent from 150 to 500 W. (NEMA, No. 56 at pp. 17–19; ULT, No. 50 at pp. 10–11) Philips commented that opportunities to further increase efficiency in this market have been explored and all economically feasible efficiency gains have already been achieved. (Philips, Public Meeting Transcript, No. 48 at p. 55) NEMA added to this point, stating that commercial markets, such as sports lighting, are already aggressively managing their costs and trying to get the most efficient equipment. (NEMA, Public Meeting Transcript, No. 48 at p. 56)

In this final rule, all of the max-tech levels are commercially available. All lower ELs analyzed are either commercially available or technologically feasible based on DOE's revised ballast modeling. To develop efficiency-level equations in this final rule, DOE utilized its own efficiency test data as well as catalog efficiency data and modeling to develop the equation forms and efficiency trends for each wattage range. The efficiency-level equations are generally designed to closely match the efficiency of the more-efficient representative units identified for each equipment class. The discussion below describes the equations used in each wattage bin. For further details, see chapter 5 of the final rule TSD.

For the lowest two wattage bins, which consist of 50 W–150 W ballasts, DOE used its own test data, as well as efficiency trends according to catalog data and modeled more-efficient units, to generate separate power-law equations for magnetic (EL1 and EL2) and electronic (EL3 and EL4) ballasts.

The next wattage bin consists of 150 W ballasts, excluding those in the currently exempt 150 W fixtures, through and including 250 W ballasts. Because EISA 2007 covered equipment in this wattage bin, DOE can only evaluate efficiencies equal to or above the existing standards to avoid backsliding. 150 W magnetic ballasts cannot be designed to meet the EISA 2007 standard of 88 percent efficiency and 175 W ballasts only reach 88 percent by using M6 steel. DOE's test data also indicated that there are no 150 W or 175 W magnetic ballasts available that exceed 88 percent efficiency. Though DOE did not test any 200 W ballasts, a review of the CCE database indicates that 200 W ballasts are typically only available at about 88 percent efficiency. Because DOE has no specific information indicating that these ballasts can be designed to be more efficient, DOE assumed that 88 percent is also the max-tech magnetic ballast efficiency for wattages up through 200 W. Thus, DOE maintained the EISA 2007 efficiency requirement of 88 percent for ELs designed to represent levels met by magnetic ballasts. DOE did not have any information available about the achievable efficiencies for 201 W–250 W ballasts, as ballasts in this range are not commercially available. Therefore, DOE gradually increased the magnetic ELs (EL1 and EL2) between 200 W and 250 W ballasts using a linear trend from 88 percent to the efficiency of the EL1 and EL2 250 W representative units. For the electronic ballast levels (EL3 and EL4), DOE continued the power-law function fit from the 50 W–150 W range to 250 W.

The next wattage bin consists of 251 W–500 W ballasts. Because the 250 W and 400 W magnetic representative units at EL1 and EL2 have the same efficiency and utilize similar design options, DOE created a flat efficiency requirement for magnetic ballasts in this wattage bin. For the electronic ballast levels (EL3 and EL4), DOE continued the power-law function fit from the 50 W–250 W range to 500 W.

The next wattage bin consists of 501 W–1000 W ballasts. DOE examined catalog data for market availability and found no electronic ballasts for general lighting applications commercially available above 500 W. Thus, there are only two ELs at this wattage range rather than four. NEMA submitted written comments indicating that different groups of ballasts have different relationships between lamp current squared and lamp wattage. (NEMA, No. 56 at p. 13) Through review of ANSI C78.81–2010 and lamp datasheets, DOE found lamps with rated wattages between 501 W and 750 W generally had different lamp voltages than lamps with rated wattages between 751 W and 1000 W, suggesting a difference in ballast efficiency trends across the 750 W threshold. Therefore, DOE used linear equations from 501 W–750 W that (1) connect to the EL1 and EL2 equations from the 251 W–500 W equipment class, and (2) connect to the least efficient 750 W ballasts on the market at 91 percent. Then from 751 W–1000 W DOE used linear equations that (1) connect to 91 percent at the low wattage end, and (2) connect to the EL1 and EL2 representative unit efficiencies at 1000 W. This approach to the 501 W–1000 W equipment class also has the advantage of encouraging purchase of lower wattage ballasts, by ensuring that commercially available options remain on the market at EL1 and EL2.

The highest wattage bin consists of 1001 W–2000 W ballasts. DOE again found no electronic ballasts in this wattage range, so there are only two levels of efficiency at the highest wattage range rather than four. After examining the efficiency trends among commercially available ballasts in this wattage bin, DOE used a flat linear equation above 1000 W due to the limited data available regarding an efficiency trend for these wattages. DOE anchored the line from the previous wattage bin's 1000 W efficiencies at EL1 and EL2 and confirmed the equation allows the representative units at 1500 W to just meet their respective ELs.

Table V.4 summarizes all of the functions and efficiencies describing each equipment class.

TABLE V.4—EFFICIENCY LEVEL DESCRIPTIONS FOR THE REPRESENTATIVE EQUIPMENT CLASSES

Representative equipment class	Rep. wattage	EL	Minimum efficiency equation† %	
≥50 W and ≤100 W	70 W	EL1	1/(1+1.33×P^(−0.346))†	
		EL2	1/(1+1.24×P^(−0.351))	
		EL3	1/(1+0.600×P^(−0.340))	
		EL4	1/(1+0.360×P^(−0.297))	
>100 W and <150 W*	150 W	EL1	1/(1+1.33×P^(−0.346))	
		EL2	1/(1+1.24×P^(−0.351))	
		EL3	1/(1+0.600×P^(−0.340))	
		EL4	1/(1+0.360×P^(−0.297))	
≥150 W** and ≤250 W	250 W	EL1	≥150 W and ≤200 W: 0.880	>200 W and ≤250 W: 0.000400×P + 0.800
		EL2	≥150 W and ≤200 W: 0.880	>200 W and ≤250 W: 0.000600×P + 0.760
		EL3	1/(1+0.600×P^(−0.340))	
		EL4	1/(1+0.360×P^(−0.297))	
>250 W and ≤500 W	400 W	EL1	0.900	
		EL2	0.910	
		EL3	1/(1+0.600×P^(−0.340))	
		EL4	1/(1+0.360×P^(−0.297))	
>500 W and ≤1000 W	1000 W	EL1	>500 W and ≤750 W: 0.0000400×P+0.880	>750 W and ≤1000 W: 0.0000840×P + 0.847
		EL2	>500 W and ≤750 W: 0.910	>750 W and ≤1000 W: 0.000104×P + 0.832
>1000 W and ≤2000 W	1500 W	EL1	0.931	
		EL2	0.936	

*Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

**Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

†P is defined as the rated wattage of the lamp the MHLF is designed to operate.

10. Design Standard

Under 42 U.S.C. 6295(hh)(4), DOE is permitted to set an energy efficiency standard based on both design and performance requirements. EISA 2007 required probe-start ballasts to be 94 percent efficient, effectively banning probe-start ballasts between 150 W and 500 W (except those 150 W ballasts exempted by EISA 2007) based on their inability to meet this performance requirement. (42 U.S.C. 6295(hh)(1)(A)(ii)) Manufacturers responded to the EISA 2007 standards by shifting their inventory to pulse-start ballasts, which are subject to less stringent standards. In the NOPR, DOE proposed a design standard that would prohibit the sale of probe-start ballasts in newly sold fixtures from 501 W–2000 W.

The Joint Comment supported standards for high-wattage fixtures and agreed that a design standard prohibiting probe-start ballasts could yield additional energy savings by allowing a customer to install fewer or lower-wattage pulse-start fixtures. If DOE found that a design standard for the highest wattage products was not feasible or cost effective, the Joint Comment urged DOE to split the highest-wattage equipment class into two classes—one for 501 W–1000 W fixtures and one for 1001 W–2000 W fixtures—such that the design standard could be applied to only 501 W–1000 W fixtures. (Joint Comment, No. 62 at p. 8)

DOE agrees that the design standard could result in energy savings through various potential energy saving pathways. As discussed in section V.A.2, in the final rule DOE has established separate equipment classes for 501 W–1000 W MHLFs and 1001 W–2000 W MHLFs. As a result, DOE analyzed the feasibility of the design standard separately for these two wattage ranges.

In the NOPR, DOE based its analysis of the design standard on the 1000 W MHLFs. For the final rule DOE continues to analyze the 1000 W MHLFs, but only as representative of the 501 W–1000 W equipment class. The Joint Comment disagreed with DOE's figure proposed in the NOPR of a 5.6 increase in lumen maintenance corresponding to a 5.6 percent reduction in normalized input system power and instead predicted higher energy savings of 12.5 percent. (Joint Comment, No. 62 at p. 8) Musco Lighting also did not agree with the 5.6 percent energy savings assumed in the NOPR, but predicted it would be a smaller percentage. Musco Lighting stated that in sports lighting applications, which are common at the higher wattage range, the lamp arc tube is horizontal or in a tilted position, yielding less projected energy savings than calculated with a vertical base up position. (Musco Lighting, Public Meeting Transcript, No. 48 at p. 180) Musco Lighting provided further data demonstrating that 1500 W probe-start start applications have greater efficiency than 1000 W or 2000 W pulse-start when operated in a horizontal position. Furthermore, Musco Lighting commented that while the probe in probe-start lamps contributes to the blackening of the arc tube in lower-wattage lamps, as the size of the arc tube increases in higher-

wattage lamps, the probe does not increase in size and thus has less of an impact. In larger arc tubes, the blackening is driven principally by the primary electrodes, which are present in pulse-start lamps as well. (Musco Lighting, No. 55 at p. 2) Philips commented that there are no efficiency differences between probe-start and pulse-start at or above 1000 W. (Philips, Public Meeting Transcript, No. 48 at p. 130) Acuity noted that the majority of the energy savings at 1000 W would come from the lamp rather than the ballast. Acuity questioned whether or not the statutory authority allows energy savings to be calculated using gains in lamp performance, as this MHLF rulemaking is based on ballast efficiency. (Acuity, Public Meeting Transcript, No. 48 at p. 173)

DOE notes that the intent of the design standard is to encourage customers to switch to reduced-wattage pulse-start from full-wattage probe-start systems due to the observation that pulse-start lamps have better lumen maintenance. For the 501 W–1000 W equipment classes, DOE has adjusted the assumption that pulse-start systems have 5.6 percent higher mean lumens which would result in 5.6 percent energy savings. DOE presents two commercially available pathways that an existing 1000 W probe-start customer could take in response to the design standard: Shifting to an 875 W pulse-start system, or staying at 1000 W and shifting to a pulse-start system. The shift to pulse-start at 1000 W would result in additional light output and no energy savings relative to a probe-start MHLF. The shift to 875 W would maintain equal lumen output and result in about 12.5 percent energy savings relative to 1000 W probe-start MHLFs.[31] This rulemaking regulates the efficiency of ballasts used in new MHLFs. Due to the increased mean lumens available in pulse-start lamps, the pulse-start lamp-and-ballast system can save energy relative to probe-start lamp-and-ballast systems. The design standard component of this final rule only regulates the ballast component of the lamp-and-ballast system.

NEMA, Venture, Musco Lighting, and ULT disagreed with DOE's proposed design standard regarding greater than or equal to 1000 W applications. (NEMA, Public Meeting Transcript, No. 48 at p. 168; Venture, Public Meeting Transcript, No. 48 at p. 170; Musco Lighting, Public Meeting Transcript, No. 48 at p. 180; Musco Lighting, No. 55 at pp. 1–3; ULT, No. 50 at p. 120) Musco Lighting pointed out that pulse-start has limited applicability above 1000 W and should not be considered at these higher wattages. (Musco Lighting, No. 55 at p. 3) ULT commented that MHLFs above 1000 W are typically probe-start and the proposed ruling would eliminate this class. ULT also added that there are no 1250 W or 1650 W pulse-start lamps. (ULT, No. 50 at p. 3) NEMA also stated that there would be a conspicuous cost increase for most other higher-wattage ballasts, including the change from probe- to pulse-start for 1001 W–2000 W. (NEMA, No. 56 at pp. 6–7) Musco Lighting additionally expressed concerns about involving 1500 W fixtures in the rulemaking because their principal use is sports lighting. Not only does sports lighting have very specific application standards requiring particularly uniform light levels and glare control that dictate specific pole locations, but also the transition from probe-start to pulse-start would require development of a 944 W system that does not currently exist. Due to this lack of existing commercially available technology, Musco Lighting stated that the proposed rule would go against 42 U.S.C. 6295(o)(4). (Musco Lighting, No. 55 at pp. 1–3) NEMA further explained that stadium fixtures for double-ended, pulse-start 1500 W and 2000 W MH lamps meet industry standards for containment in the event of lamp rupture, and provide a UV attenuation barrier and lens interlock, while meeting league and television network requirements for on-field illumination and uniformity. Therefore, NEMA contended that there are no direct replacements for this equipment. Elimination of the lamp type used in such fixtures would result in significant retrofitting or replacement with lamps less suitable for the application, costs that NEMA stated must also be added to feasibility estimates. (NEMA, No. 56 at p. 7)

After establishing a new equipment class for 1001 W to 2000 W fixtures, DOE reanalyzed the merits of the design standard for the 1500 W representative wattage. DOE agrees that the design standard banning probe-start lamps should not be analyzed for fixtures above 1000 W because pulse-start systems in this wattage range do not have increased lumen maintenance relative to probe-start systems. Therefore, there are no commercially available pulse start options that would offer the same light output with reduced energy consumption (industry considers changes in light output of greater than 10 percent to be perceptible by the average customer). Thus, in this final rule, DOE did not analyze a design standard in the 1001 W–2000 W equipment classes.

NEMA expanded upon its view that DOE's proposed efficiency requirements would eliminate probe-start ballasts and lamps. NEMA argued that the facility of starting probe-start lamps in the greater than 1000 W category is a highly desirable performance characteristic. NEMA described that sports lighting owners and operators prefer the ballast and other serviceable components to be located in the base of the fixture mast, for ease of maintenance and safety. With probe-start technology, the 400 V starting signal is able to travel up the mast and reliably ignite the lamp. The 3000 V–4000 V microsecond pulses from pulse-start ballasts are attenuated by long wires over the 30 ft.–40 ft. height of the masts so that the high pressure starting gas in pulse-start lamps may not ignite. NEMA noted that moisture could also cause attenuation with pulse-start ballasts, while probe-start ballasts are less susceptible to the effects of weather. NEMA acknowledged that pulse-start remote electronic igniters are available at a considerable cost premium. However, as the fixture housing is not designed for them, there are thermal concerns and the igniters themselves are difficult to access for maintenance. (NEMA, No. 56 at p. 7)

Philips, NEMA, Musco Lighting, and ULT further commented that a ruling that discontinued probe-start ballasts and lamps would create problems. There are currently no pulse-start options for MHLFs installed in high-mast locations; to make the technology work would require the addition of an igniter at the top of the pole, which would add costs and complexity. (Philips, Public Meeting Transcript, No. 48 at pp. 166, 169; NEMA, Public Meeting Transcript, No. 48 at p. 166; NEMA, No. 56 at p. 19; Musco Lighting, No. 48, Public Meeting Transcript, at p. 167; ULT, No. 50 at p. 3) ULT explained that applications at 1000 W or higher generally have a ballast-to-lamp distance that is too long for standard pulse-start ballasts and would require the addition of a special igniter and a cost adder of $10-$15 per ballast. (ULT, No. 50 at p. 12) Musco Lighting stated that the additional costs required to change from a probe-start to pulse-start system are much higher than DOE estimated. (Musco Lighting, No. 55 at p. 3) NEMA asserted that mandating ELs that preclude any technology but pulse-start electronically ballasted equipment would create increased maintenance

[31] The estimate of 12.5 percent energy savings comes from reducing a 1000 W system by 12.5 percent to get to 875 W. However, since 875 W ballasts are characteristically less efficient than 1000 W ballasts, the total energy savings will in reality be slightly less than 12.5 percent.

and material costs due to surge and lightning resistance, increased fixture size and price, added weather resistance, remote igniter installation, and the higher maintenance cost and considerations of high-mast lighting fixtures. NEMA suggested excluding such equipment from energy conservation standards in order to avoid these issues. (NEMA, Public Meeting Transcript, No. 48 at p. 168; NEMA, No. 56 at p. 8) NEMA also noted that given the previous considerations, including greater than or equal to 1000 W fixtures in the rulemaking, would go against 42 U.S.C. 62955(o)(4), as the adoption of these standards would be "likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding." (NEMA, No. 56 at pp. 6–7)

For 1000 W high-mast applications, DOE found that remote starting is an option that is commercially available using pulse-start technology. As mentioned in comments, this would require the addition of a remote igniter at the top of the pole. DOE has accounted for the added equipment costs that would be associated with using pulse-start technology in 1000 W applications requiring high-mast fixtures. DOE notes that the design standard would not result in a push towards electronic levels, as the design standard is only considered for fixtures between 501 W and 1000 W, where electronic ballasts are not commercially available, and thus not analyzed.

NEMA commented that DOE appears to be applying incandescent technology to ballast efficiency and lamp efficacy. NEMA and ULT asserted that a ballast will have difficulties operating at wattages other than its rating and that such operation is a violation of its intended use and should not be considered. (NEMA, No. 56 at p. 15; ULT, No. 50 at p. 8). DOE agrees that ballasts would have difficulty operating at wattages other than those listed by the manufacturer. As mentioned previously, in this final rule DOE analyzed the design standard so that 1000 W probe-start systems would be replaced with either 875 W or 1000 W pulse-start systems. The use of 875 W ballasts would be with 875 W lamps, as DOE is not modeling the design standard to use a reduced-wattage lamp on a full-wattage ballast in this MHLF rulemaking. DOE continues to agree that ballasts will have difficulties operating lamps at wattages other than their rating, and does not analyze any such scenarios in this final rule.

EEI expressed concerns that an outright ban on probe-start ballasts may hinder technological developments and higher-efficiency possibilities for the technology. (EEI, Public Meeting Transcript, No. 48 at p. 183) Further, NEMA and ULT opposed the ban, as 175 W to 400 W probe-start ballasts are already practically prohibited by existing regulation. NEMA and ULT stated that any limited remaining market should be maintained for desirable performance characteristics where it is deemed necessary. (NEMA, No. 56 at p. 19; ULT, No. 50 at p. 12)

DOE recognizes that probe-start MH ballasts have the remote-starting feature that is not provided with standard pulse-start MH ballasts. However, as discussed previously, DOE has found that pulse-start 1000 W systems can provide the remote-starting feature with the addition of a remote igniter. DOE accounts for the increased cost of the remote-start pulse-start system in section V.C.12 of this notice.

In summary, this final rule analyzes a design standard from 501 W–1000 W, but not from 1001 W–2000 W. In the 1001–2000 W equipment class pulse start systems do not have better lumen maintenance compared to probe start systems. At 501 W–1000 W, however, DOE is still analyzing a design standard banning probe-start ballasts. Customers previously purchasing 1000 W probe-start fixtures would have the option of purchasing an 875 W pulse-start system with 12.5 percent energy savings while maintaining light output, or adopting a compliant 1000 W pulse-start system.

11. Scaling to Equipment Classes Not Analyzed

DOE did not directly analyze ballasts tested at an input voltage of 480 V. Thus, it was necessary to develop a scaling relationship to establish ELs for these equipment classes. To do so in the NOPR, DOE compared quad-voltage ballasts from the representative equipment classes to their 480 V ballast counterparts using catalog data over all representative wattages at various efficiencies. In the NOPR, DOE found the average reduction to ballast efficiency to be 0.6 percent. Therefore, DOE proposed applying this reduction (in the form of a multiplier of 0.994) to develop ELs for the 480 V ballasts. For the 150 W–250 W equipment classes, DOE made adjustments to resulting scaled equations to ensure all ELs were equal to or more stringent than the existing standards (see chapter 5 of the final rule TSD for additional detail).

ULT and NEMA commented that a flat 0.6 percent efficiency gap between quad-voltage and dedicated 480 V fixtures cannot be used across all wattages. In lower wattages, this difference can be much higher, greater than 2 percent. (ULT, Public Meeting Transcript, No. 48 at p. 209; NEMA, No. 56 at p. 19) ULT and NEMA proposed a scaling factor of 2 percent for wattages less than or equal to 150 W, and 1 percent for wattages greater than 150 W (in the form of a subtraction of 2 percentage points and 1 percentage point from the representative equipment class ELs, respectively). (ULT, No. 50 at pp. 11–12; NEMA, No. 56 at p. 19) Musco Lighting noted that the 480 V scaling factor should be a 1 percent reduction instead of 0.6 percent to account for the inability to measure ballast efficiency with more precision than a whole percentage point. (Musco Lighting, No. 55 at p. 4)

In the final rule, DOE analyzed the test data and agreed that the difference in efficiency between ballasts tested at 480 V and ballasts tested at other input voltages changes based on wattage. At lower wattages, ballasts are more compact and less efficient, and the difference in efficiency between the voltages is greater. Because of this correlation, DOE has adjusted the scaling factor used to scale efficiency levels from representative equipment classes to the 480 V equipment classes from the 0.6 percent reduction in the NOPR to the values shown in Table V.5. As in the NOPR, DOE again compared quad-voltage ballasts to their 480 V ballast counterparts using catalog data over all representative wattages. DOE found the average reduction to ballast efficiency changed based on two wattage ranges: 50 W–150 W and 151 W–1000 W. For 50 W–150 W, DOE found the average reduction in ballast efficiency to be less than the 2.0 percent proposed by NEMA. However, DOE did find some instances in which the difference in efficacy was as high or higher than that noted by NEMA. Therefore, DOE determined a scaling factor of 2.0 percent (in the form of a subtraction of 2 percent from the representative equipment class ELs) to be appropriate from 50 W–150 W. Subtracting 2.0 percent across all wattages from 50 W–150 W, instead of applying a scaling multiplier to the EL equations, also aligns with DOE's observation that the difference in efficiency between 480 V ballasts and quad-voltage ballasts is greater at lower wattages. For 150 W–1000 W, DOE also found the average reduction to ballast efficiency to be less than the 1.0 percent

proposed by NEMA. However DOE did find some instances in which the difference in efficacy was as high or higher than that noted by NEMA. Therefore, DOE determined a scaling factor of 1.0 percent (in the form of a subtraction of 1 percent from the representative equipment class ELs) to be appropriate from 151 W–1000 W. As with the 50 W–150 W range, DOE applied this scaling factor as a subtraction from the representative equipment class ELs instead of as a multiplier. Even though the 1001 W–2000 W equipment class no longer shows a difference in efficiency between 480 V and non-480 V classes, DOE continues to consider the 480 V and non-480 V equipment classes separately for the purposes of this rulemaking. This separation allows DOE to continue comparing consistent representative classes, of ballasts not tested at 480 V, for each wattage bin. Additionally, for the 150 W–250 W equipment classes, DOE made adjustments to the resulting scaled equations to ensure all ELs were equal to or more stringent than the existing standards (see chapter 5 of the final rule TSD for additional detail).

TABLE V.5—FINAL RULE SCALING FACTORS

Wattage range	Scaling factor (percent)
50 W–150 W	2.0
151 W–1000 W	1.0
1001 W–2000 W	0.0

12. Manufacturer Selling Prices

a. Manufacturer Production Costs

DOE developed the MSPs for MHLFs and MH ballasts by determining an MPC, either through a teardown or retail pricing analysis, and then applying a manufacturer markup to arrive at the MSP. For the NOPR, DOE conducted teardown analyses on a total of 32 commercially available MH ballasts and eight MHLFs. Using the information from these teardowns, DOE summed the direct material, labor, and overhead costs used to manufacture a MHLF or MH ballast, to calculate the MPC.[32] For further details on this analysis, see chapter 5 of the final rule TSD.

APPA noted that if this rulemaking requires larger and heavier ballasts, the replacement costs would increase substantially and have a large effect on the LCC and PBP analyses since the fixture may need to be replaced. (APPA, No. 51 at p. 7) As described in section III.A, this rulemaking only covers ballasts in new fixtures. A replacement ballast for an existing fixture would not need to comply with DOE standards. As described in section V.C.8, DOE also notes that the ballasts needed to meet the standards adopted by this final rule are not notably larger than the baseline ballasts. Efficiency levels based on magnetic ballasts are either based on commercially available ballasts, or modeled using the constraint that ballast size cannot increase relative to less efficient commercially available designs. As such, DOE concluded fixtures would not need to be redesigned to account for an increase in ballast size. See section V.F of this notice for details about the costs that are accounted for in the LCC and PBP analyses.

ULT commented that the fixture price assumptions are too low, as a majority of the fixtures would have to be redesigned, requiring engineering time, new tools, and testing time. (ULT, No. 50 at p. 15) DOE's final fixture prices account for the MPC of the fixture, as detailed in chapter 5 of the final rule TSD. DOE also determined that for the levels analyzed in this rulemaking, fixtures would not be required to be substantially redesigned. Further, any costs associated with redesign, tooling, testing and the general manufacturing process are accounted for in the MIA as detailed in section V.I of this notice.

b. Empty Fixture Costs

DOE conducted fixture teardowns for the NOPR to determine appropriate empty fixture prices. When referring to the "empty fixture" component of a MHLF, DOE means the lamp enclosure and optics. The empty fixture does not include the ballast or lamp. DOE added the other components required by the system (including ballasts and any cost adders associated with electronically ballasted systems) and applied appropriate markups to get the final full fixture MSP. In the NOPR, a representative fixture price was developed for each wattage (using the same MSP for indoor and outdoor fixtures), resulting in five unique fixture prices to account for the five representative wattages.

As detailed in section V.C.4 of this notice, DOE has expanded its analysis of representative fixtures in the final rule to account for the varying fixture types used in indoor and outdoor applications. This new division allows DOE to develop separate empty fixture prices for indoor and outdoor fixtures, and thus take the weather protection built into outdoor fixtures into account. These new empty fixture MPCs can be found in chapter 5 of the final rule TSD. The updated pricing results in 12 unique empty fixture prices, namely an indoor and an outdoor price for each of the six representative wattages.

c. Incremental Costs for Electronically Ballasted MHLFs

After determining baseline MH ballast and fixture MPCs, DOE considered whether transitioning from magnetic to electronic ballast technology would require any further ballast or fixture design changes to accommodate the electronic ballast or maintain similar utility to the baseline magnetic ballast. In the NOPR, DOE proposed three sources of incremental costs: (1) Outdoor transient protection, (2) thermal management, and (3) 120 V auxiliary power functionality.

Transient Protection

DOE recognizes the necessity for outdoor fixtures to be able to withstand at least 10 kV voltage transients. While MHLFs with magnetic ballasts are robust and do not require any additional devices or enhancements to withstand these transients, based on its evaluation of commercially available MHLFs, DOE finds that fixtures with electronic ballasts usually require additional design features in order to have adequate protection. Some manufacturers indicated that a portion of their electronic ballasts already have surge protection built in, but most electronic ballasts are only rated for 2.5 kV–6 kV voltage spikes. In the NOPR, DOE proposed an incremental fixture cost of $19 for 10 kV inline (external to the ballast) surge protection for electronically ballasted outdoor fixtures. CA IOUs and the Joint Comment supported DOE's approach to modeling the incremental cost for electronic ballasts over magnetic ballasts to account for 10 kV surge protection. (CA IOUs, No. 54 at pp. 3–7; CA IOUs, Public Meeting Transcript, No. 48 at p. 202; Joint Comment, No. 62 at pp. 4–5)

In the final rule, DOE updated the price of 10 kV voltage transient protection devices. Based on a review of selling prices from transient manufacturers, DOE assigned a cost adder to manufacturers of $10.31 for 10 kV inline surge protection for electronic ballasts, as most electronic ballasts do not have this feature built in. The $10.31 cost adder reflects a high volume purchase, which would be representative of a fixture manufacturer. As such, DOE applies this adder to the fixture MPC for fixtures that require voltage surge protection. DOE also

[32] When viewed from the company-wide perspective, the sum of all material, labor, and overhead costs equals the company's sales cost, also referred to as the cost of goods sold.

assigned a cost to end-users of $21.45 to purchase a replacement voltage transient protection device at a single unit quantity.

In response to public comment, DOE researched indoor industrial fixtures and found these fixtures can also be subject to voltage surges. DOE has thus accounted for the issue of indoor electronic ballasts experiencing voltage surges in these industrial applications. Specifically, DOE analyzes the indoor industrial applications that require additional surge protection as an LCC subgroup. In order for electronic ballasts to be used in these applications, the voltage transient device costs were added to total fixture MSPs in the subgroup. The costs for the transient protection devices for electronic ballasts assigned to the manufacturer and the end user are the same for indoor industrial applications as for outdoor applications. Additionally, when these surge protection devices are compromised from repeated transient events, the additional maintenance and replacement are incorporated in the LCC analysis and NIA.

Thermal Management

Electronic ballasts are more vulnerable than magnetic ballasts to high ambient temperatures which, if not managed well, can cause premature ballast failure. In order to correct for this difference, fixtures housing electronic ballasts would need to be redesigned to account for thermal management in both indoor and outdoor applications. Manufacturers must design new and often larger brackets, and apply additional potting material to create an adequate thermal contact between the ballast and fixture. During interviews, manufacturers gave DOE information about the cost to add thermal management to fixtures with electronic ballasts. In aggregate, manufacturers indicated a 20 percent increase in fixture MPCs associated with thermal management. Additionally, DOE conducted teardown analyses of empty MHLFs. Through analysis of pairs of fixtures designed for electronic ballasts and fixtures designed for comparable magnetic ballasts, DOE also found an approximately 20 percent increase in fixture MPCs to include thermal management for electronic ballasts. Accordingly, in the NOPR cost analysis, all electronically ballasted MHLFs incur a 20 percent incremental cost to the empty fixture MPCs.

Philips and Georgia Power both expressed concerns that the MSP will increase more substantially than DOE projected. (Philips, Public Meeting Transcript, No. 48 at p. 207; Georgia Power, Public Meeting Transcript, No. 48 at p. 207) Philips emphasized that DOE's 20 percent figure for electronic ballasts in outdoor fixtures is understated and would become much higher with pole, fixture, and ballast redesign. However, CA IOUs and the Joint Comment supported DOE's approach to modeling the incremental cost for electronic ballasts over magnetic ballasts to account for thermal management and the potential need for fixture redesign. (CA IOUs, No. 54 at pp. 3–4; CA IOUs, Public Meeting Transcript, No. 48 at p. 202; Joint Comment, No. 62 at pp. 4–5)

As previously mentioned, any price increases required for MHLFs are accounted for in this MSP analysis, while any capital conversion and redesign costs are addressed in the MIA (see section V.I of this notice). DOE has determined that ballast size and weight are not required to change in response to the ELs analyzed, so DOE did not analyze a change in pole size or cost. DOE believes that a cost adder for thermal management is necessary, and given that the costs cited by manufacturers are either not required or are accounted for in another part of the analysis, DOE continues to apply a 20 percent increase in fixture MPCs to reflect thermal management for electronic ballasts

120 V Auxiliary Tap

For indoor applications, a number of magnetic ballasts include a 120 V auxiliary tap. This output is used to operate an emergency incandescent lamp after a temporary loss of power and while the MH lamp is still too hot to restart. These taps are generally required for only one out of every ten indoor lamp fixtures. A 120 V tap is easily incorporated into a magnetic ballast due to its traditional core and coil design, and incurs a negligible incremental cost. Electronic ballasts, though, require additional design to add this 120 V auxiliary power functionality. Using a combination of manufacturer information and market research, DOE proposed in the NOPR that a representative value for electronic ballasts to incorporate this auxiliary tap is $7.50. Because this functionality is only needed for 10 percent of ballasts in indoor fixtures, that number was multiplied by 0.10 to get an incremental ballast cost of $0.75 per indoor ballast.

ULT questioned why DOE scaled down the price of an auxiliary power 120 V tap using a 1:10 ratio just because 10 percent of indoor fixtures require the auxiliary power functionality. (ULT, No. 50 at p. 14) Philips commented that auxiliary power is not always available for electronic ballasts and would require an additional transformer, increasing costs. (Philips, Public Meeting Transcript, No. 48 at p. 189)

DOE scaled down the price of an auxiliary power 120 V tap using a 1:10 ratio because that was the simplest way to characterize the cost that the average fixture will incur when adding this functionality. Based on manufacturer feedback, DOE determined that 10 percent of indoor fixtures require auxiliary 120 V power functionality. Therefore, this method continued to be used to account for these costs in this final rule. DOE agrees that the auxiliary power is not always available with electronic ballasts, and therefore included this incremental ballast cost to account for integrating the additional tap. DOE maintains that the representative value for electronic ballasts to incorporate the auxiliary tap is $7.50. As mentioned previously, as this functionality is only needed for 10 percent of ballasts in indoor fixtures, the resulting incremental ballast cost is $0.75 per indoor ballast.

d. Costs Associated With the Design Standard

In the NOPR, DOE analyzed a design standard banning probe-start ballasts for fixtures greater than 500 W. Pulse-start MH systems require an igniter to start the lamp, while probe-start MH systems do not. In DOE's NOPR cost model, the additional cost of this igniter in pulse-start systems was the only source of cost difference between probe- and pulse-start systems.

Musco Lighting commented that at 1500 W, the cost to shift from a probe-start to a pulse-start system would be much higher than DOE estimated. Musco estimated a more representative value would be four times the incremental cost currently utilized and noted that the igniter could lead to increased maintenance costs. (Musco Lighting, No. 55 at p. 3)

As noted in section V.C.10 of this notice, DOE has chosen to not analyze a design standard for lamps above 1000 W. Therefore, the costs of a transition to pulse-start technology at 1500 W are no longer needed for the final rule analysis.

However, DOE did find that at 1000 W, the design standard could create challenges with certain customers switching to pulse-start technology. Customers who use high-mast applications often see probe-start systems as preferable because they can be easily mounted remotely. This means that the ballast can be at the bottom of the pole for easy maintenance, while the lamp is operated at the top of the pole. In order for a pulse-start system to allow

for this remote mounting, DOE found that there are commercially available remote-start igniters that allow pulse-start ballasts to also be remotely mounted. This comes at increased cost due to the addition of this more complex igniter at the top of the pole. When comparing commercially available standard and remote-start igniters, DOE found that remote-start igniter costs were about two times greater. As such, when modeling customers who require remote starting in design standard scenarios, DOE applied a multiplier of 2.07 to the igniter costs.

e. Manufacturer Markups

The last step in determining MSPs is development and application of manufacturer markups to scale the MPCs to MSPs. DOE developed initial manufacturer markup estimates by examining the annual SEC 10–K reports filed by publicly traded manufacturers of MH ballasts and MHLFs, among other products. Based on feedback from manufacturers, in the NOPR DOE proposed separate markups for ballast manufacturers (1.47) and fixture manufacturers (1.58). DOE also assumed that fixture manufacturers apply the 1.58 markup to the ballasts used in their fixtures rather than to only the empty fixtures. In aggregate, the markup also accounted for the different markets served by fixture manufacturers. The 1.47 markup for ballast manufacturers applied only to ballasts sold to fixture original equipment manufacturers (OEMs) directly impacted by this rulemaking. For the purpose of the LCC and NIA analysis, DOE assumed a higher markup of 1.60 for ballasts that are sold to distributors for the replacement market. Receiving no comments to the contrary, DOE continued using these manufacturer markups in the final rule.

D. Markups To Determine Equipment Price

By applying markups to the MSPs estimated in the engineering analysis, DOE estimated the amounts customers would pay for baseline and more-efficient equipment. At each step in the distribution channel, companies mark up the price of the equipment to cover business costs and profit margin. Identification of the appropriate markups and the determination of customer equipment price depend on the type of distribution channels through which the equipment moves from manufacturer to customer.

1. Distribution Channels

Before it could develop markups, DOE needed to identify distribution channels (*i.e.,* how the equipment is distributed from the manufacturer to the end user) for the MHLF designs addressed in this rulemaking. In an electrical wholesaler distribution channel, DOE assumed the fixture manufacturer sells the fixture to an electrical wholesaler (*i.e.,* distributor), who in turn sells it to a contractor, who sells it to the end user. In a contractor distribution channel, DOE assumed the fixture manufacturer sells the fixture directly to a contractor, who sells it to the end user. In a utility distribution channel, DOE assumed the fixture manufacturer sells the fixture directly to the end user (*i.e.,* electrical utility).

2. Estimation of Markups

To estimate wholesaler and utility markups, DOE used financial data from 10–K reports from publicly owned electrical wholesalers and utilities. DOE's markup analysis developed both baseline and incremental markups to transform the fixture MSP into an end-user equipment price. DOE used the baseline markups to determine the price of baseline designs. Incremental markups are coefficients that relate the change in the MSP of higher-efficiency designs to the change in the wholesaler and utility sales prices, excluding sales tax. These markups refer to higher-efficiency designs sold under market conditions with new and amended energy conservation standards.

In the NOPR, DOE assumed a wholesaler baseline markup of 1.23 and a contractor baseline markup of 1.13, for a total wholesaler distribution channel baseline markup of 1.39. DOE also assumed utility baseline markups of 1.00 and 1.13 for the utility distribution channel in which the manufacturer sells a fixture directly to the end user, and the channel in which a manufacturer sells a fixture to a contractor who in turn sells it to the end user, respectively.

The sales tax represents state and local sales taxes applied to the end-user equipment price. DOE obtained state and local tax data from the Sales Tax Clearinghouse.[33] These data represent weighted averages that include state, county, and city rates. DOE then calculated population-weighted average tax values for each census division and large state, and then derived U.S. average tax values using a population-weighted average of the census division and large state values. For the NOPR, this approach provided a national average tax rate of 7.13 percent.

3. Summary of Markups

Table V.6 summarizes the markups at each stage in the distribution channels and the overall baseline and incremental markups, and sales taxes, for each of the three identified channels.

TABLE V.6—SUMMARY OF FIXTURE DISTRIBUTION CHANNEL MARKUPS

	Wholesaler distribution		Utility distribution			
			Via wholesaler & contractor		Direct to end user	
	Baseline	Incremental	Baseline	Incremental	Baseline	Incremental
Electrical Wholesaler (Distributor)	1.23	1.05	(1)	(1)	(1)	(1)
Utility	(1)	(1)	1.00	1.00	1.00	1.00
Contractor or Installer	1.13	1.13	1.13	1.13	(1)	(1)
Sales Tax	1.07		1.07		1.07	
Overall	1.49	1.27	1.21	1.21	1.07	1.07

[1] Not applicable.

[33] The Sales Tax Clearinghouse. Available at *https://thestc.com/STRates.stm.* (Last accessed June 24, 2013.)

Using these markups, DOE generated fixture end-user prices for each EL it considered, assuming that each level represents a new minimum efficiency standard. Chapter 6 of the final rule TSD provides additional detail on the markups analysis.

E. Energy Use Analysis

For the energy use analysis, DOE estimated the energy use of metal halide lamp fixtures in actual field conditions. The energy use analysis provided the basis for other DOE analyses, particularly assessments of the energy savings and the savings in operating costs that could result from DOE's adoption of new and amended standard levels.

To develop annual energy use estimates for the August 2013 NOPR, DOE multiplied annual usage (in hours per year) by the lamp-and-ballast system input power (in watts). DOE characterized representative lamp-and-ballast systems in the engineering analysis, which provided measured input power ratings. To characterize the country's average use of fixtures for a typical year, DOE developed annual operating hour distributions by sector, using data published in the 2010 LMC, the Commercial Building Energy Consumption Survey (CBECS),[34] and the Manufacturer Energy Consumption Survey (MECS).[35] 78 FR 51464, 51501 (Aug. 20, 2013).

Musco Lighting and NEMA commented that metal halide lamp fixtures over 1000 W–particularly 1500 W fixtures—are principally confined to sports lighting applications, and Musco Lighting noted that their monitoring data indicates average usage of 250 hours per year for these fixture types. (Musco Lighting, No. 55 at pp. 1, 4; NEMA, No. 56 at pp. 6–7) The CA IOUs stated that high-wattage MH fixtures are also commonly used in high mast applications, with operating hours similar to other outdoor lighting applications. (CA IOUs, No. 54 at p. 2) DOE acknowledges that high-wattage MH fixtures may be used in high mast applications but notes that the 2010 LMC indicates an average MH lamp wattage of less than 250 W for roadway and parking applications, suggesting a negligible contribution by high mast lighting. As discussed in section V.A.2, DOE created a separate 1500 W equipment class for this final rule to address the unique design features and application of these fixture types. Musco did not provide detailed operating hours data with their written comments; however, NEMA cited the 2010 LMC estimate of 1 hour per day for stadium lighting as reasonable for MHLF applications greater than 1000 W. DOE agrees with NEMA that this 2010 LMC estimate is reasonable for sports lighting applications, and DOE assumed annual operation of 350 hours per year (based on the actual LMC value of 0.958 hours per day) for the 1500 W equipment class in its final rule energy use analysis.

The August 2013 NOPR analysis assumed full operating power and no dimmed operation to estimate MHLF energy use. 78 FR 51464, 51502 (Aug. 20, 2013). DOE received no comments regarding its operating power assumption, and retained its approach for the energy use analysis in today's final rule. Chapter 7 of the final rule TSD provides a more detailed description of DOE's energy use analysis.

F. Life-Cycle Cost and Payback Period Analyses

DOE conducted the LCC and PBP analysis to evaluate the economic effects of potential energy conservation standards for metal halide lamp fixtures on individual customers. For any given efficiency level, DOE measured the PBP and the change in LCC relative to an estimated baseline equipment efficiency level. The LCC is the total customer expense over the life of the equipment, consisting of purchase, installation, and operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounted future operating costs to the time of purchase and summed them over the lifetime of the equipment. The PBP is the estimated amount of time (in years) it takes customers to recover the increased purchase cost (including installation) of more efficient equipment through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost (normally higher) by the change in average annual operating cost (normally lower) that results from the more efficient standard.

Inputs to the calculation of total installed cost include the cost of the equipment—which includes MSPs, distribution channel markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, equipment lifetimes, discount rates, and the year that compliance with new and amended standards is required. To account for uncertainty and variability, DOE created distributions for selected inputs, including operating hours, equipment lifetimes, electricity prices, discount rates, and sales tax rates. For example, DOE created a probability distribution of annual energy consumption in its energy use analysis, based in part on a range of annual operating hours. The operating hour distributions capture variations across building types, lighting applications, and metal halide systems for three sectors (commercial, industrial, and outdoor stationary). In contrast, fixture MSPs were specific to the representative designs evaluated in DOE's engineering analysis, and price markups were based on limited publicly available financial data. Consequently, DOE used discrete values instead of distributions for these inputs.

The computer model DOE uses to calculate the LCC and PBP, which incorporates Crystal Ball (a commercially available software program), relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and fixture user samples. The final rule TSD chapter 8 and its appendices provide details on the spreadsheet model and all the inputs to the LCC and PBP analysis.

Table V.7 summarizes the approach and data DOE used to develop inputs to the LCC and PBP calculations for the August 2013 NOPR as well as the changes made for today's final rule. The subsections that follow discuss the calculation inputs and DOE's changes to them.

[34] U.S. Department of Energy, Energy Information Agency. *Commerciol Building Energy Consumption Survey: Micro-Level Dato, File 2 Building Activities, Speciol Meosures of Size, ond Multi-building Facilities.* 2003. Available at *www.eia.doe.gov/emeu/cbecs/public_use.html.*

[35] U.S. Department of Energy, Energy Information Agency. *Manufocturing Energy Consumption Survey, Toble 1.4: Number of Estoblishments Using Energy Consumed for All Purposes.* 2006. Available at *www.eio.doe.gov/emeu/mecs/mecs2006/2006tobles.html.*

TABLE V.7—SUMMARY OF INPUTS AND KEY ASSUMPTIONS IN THE LCC AND PBP ANALYSIS *

Inputs	NOPR	Changes for the final rule
Equipment Cost	Derived by multiplying MHLF MSPs by distribution channel markups and sales tax.	No change.
Installation Cost	Calculated costs using estimated labor times and applicable labor rates from "RS Means Electrical Cost Data" (2009) and U.S. Bureau of Labor Statistics.	Calculated costs using estimated labor times and applicable labor rates from "RS Means Electrical Cost Data" (2013); Sweets Electrical Cost Guide 2013; and U.S. Bureau of Labor Statistics.
Annual Energy Use	Determined operating hours separately for indoor and outdoor fixtures. Used lighting market data: 2010 LMC (2012).	No change.
Energy Prices	Electricity: Based on EIA's Form 826 data for 2012 Variability: Energy prices determined at state level; incorporated off-peak electricity prices in the Monte Carlo analysis.	No change.
Energy Price Projections	Projected using *AEO2013*	No change.
Replacement Costs	Included labor and material costs for lamp and ballast replacement through the end of their lifetimes.	No change.
Equipment Lifetime	Ballasts: Assumed 50,000 hours for magnetic ballasts and 40,000 hours for electronic ballasts.	Ballasts: No change.
	Fixtures: Assumed 20 years for indoor fixtures and 25 years for outdoor fixtures.	Fixtures: No change.
	Variability: Incorporated lamp and ballast lifetimes in the Monte Carlo analysis.	Variability: Incorporated lamp, ballast and fixture lifetimes in the Monte Carlo analysis.
Discount Rates	Commercial/Industrial: Developed a distribution of discount rates for each end-use sector.	Commercial/Industrial: No change.
	Outdoor Stationary: Developed a distribution of discount rates for each end-use sector.	Outdoor Stationary: No change.

* References for the data sources mentioned in this table are provided in the sections following the table or in chapter 8 of the final rule TSD.

1. Equipment Cost

To calculate customer equipment costs, DOE multiplied the MSPs developed in the engineering analysis by the distribution channel markups described in section V.D.1 (along with sales taxes). DOE used different markups for baseline equipment and higher efficiency equipment because the markups estimated for incremental costs differ from those estimated for baseline models. For the August 2013 NOPR, DOE also examined historical price data for various appliances and equipment that—along with economic literature—suggest that the real costs of these products may in fact trend downward over time, partially because of "learning" or "experience." [36] 78 FR 51464, 51503 (Aug. 20, 2013).

On February 22, 2011, DOE published a notice of data availability (February 2011 NODA; 76 FR 9696) stating that DOE may consider improving regulatory analysis by addressing equipment price trends. DOE notes that learning-curve analysis characterizes the reduction in production cost mainly associated with labor-based performance improvement and higher investment in new capital equipment at the microeconomic level. Experience-curve analysis tends to focus more on entire industries and aggregates over various causal factors at the macroeconomic level: "Experience curve" and "progress function" typically represent generalizations of the learning concept to encompass behavior of all inputs to production and cost (*i.e.*, labor, capital, and materials). The economic literature often uses these two terms interchangeably. The term "learning" is used here to broadly cover these general macroeconomic concepts.

For the August 2013 NOPR and consistent with the February 2011 NODA, DOE examined two methods for estimating price trends for metal halide lamp fixtures: using historical producer price indices (PPIs), and using projected price indices (called deflators). With PPI data, DOE found both positive and negative real price trends, depending on the specific time period examined, and did not use this method to adjust fixture prices. DOE instead adjusted fixture prices using deflators used by EIA to develop the *AEO2011*. When adjusted for inflation, the deflator-based price indices decline from 100 in 2010 to approximately 75 in 2046. 78 FR 51464, 51503 (Aug. 20, 2013).

DOE received no comments related to equipment price trends, and retained its deflator-based approach to adjust fixture prices for this final rule. Using updated (*AEO2013*) deflators, DOE estimated that the price indices decline from 100 in 2010 to approximately 90 in 2046. A more detailed discussion of price trend modeling and calculations is provided in appendix 8B of the final rule TSD.

2. Installation Cost

Installation costs for metal halide lamp fixtures include the costs to install the fixture, maintain the ballast, and replace the lamp. For the August 2013 NOPR, DOE used data collected for its July 2010 HID lamps determination,[37] labor rates for electricians from *RS Means*,[38] and other research to estimate the installation costs. DOE assumed that installation costs varied between equipment classes as a function of fixture size and mounting locations but were the same between efficiency levels within a given equipment class. For maintenance costs, DOE employed a methodology that allows the use of annualized maintenance costs while maintaining the integrity of the NPV calculations in the NIA. 78 FR 51464, 51503 (Aug. 20, 2013).

DOE received comments that larger ballasts and housings—and larger poles required for outdoor fixtures—would increase costs and payback periods for higher-efficiency designs. (Acuity Brands, Public Meeting Transcript, No. 48 at p. 60; GE, Public Meeting

[36] A draft paper, *Using the Experience Curve Approach for Appliance Price Forecasting*, posted on the DOE Web site at *www.eere.energy.gov/buildings/appliance_standards*, provides a summary of the data and literature currently available to DOE that is relevant to price forecasts for selected appliances and equipment.

[37] U.S. Department of Energy–Office of Energy Efficiency and Renewable Energy. *Energy Conservation Program for Consumer Equipment: Preliminary Technical Support Document: High-Intensity Discharge Lamps.* 2010. Washington, DC. Available at <*www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/60*>.

[38] R.S. Means Company, Inc. *2010 RS Means Electrical Cost Data.* 2010. Kingston, MA.

Transcript, No. 48 at pp. 231–232; NEMA, No. 56 at p. 2) As discussed previously in section V.C of this final rule, DOE's engineering analysis indicated that higher-efficiency fixture designs would not incur significant increases in housing size, effective projected area, or required pole size. DOE, therefore, did not include the added cost of larger poles in the installation costs for higher efficiency fixture designs. For this final rule, DOE also referenced Sweets Electrical Cost Guide [39] in developing installation cost estimates for the LCC and PBP analysis. For further detail, see chapter 8 of the final rule TSD.

3. Annual Energy Use

As discussed in section V.E, DOE estimated the annual energy use of representative metal halide systems using system input power ratings and sector operating hours. For the August 2013 NOPR, DOE based the annual energy use inputs to the LCC and PBP analysis on weighted average annual operating hours. 78 FR 51464, 51503 (Aug. 20, 2013). For this final rule, DOE based the annual energy use inputs on sectoral operating hour distributions (commercial, industrial, and outdoor stationary sectors), with the exception of a discrete value (350 hours per year) for the 1500 W equipment class that is primarily limited to sports lighting. DOE used operating hour (and, by extension, energy use) distributions to better characterize the potential range of operating conditions faced by MHLF customers.

4. Energy Prices

For the August 2013 NOPR, DOE estimated electricity prices for commercial, industrial and outdoor stationary sectors by state using data from EIA Form 826, "Monthly Electric Utility Sales and Revenue Data, 2011." 78 FR 51464, 51503 (Aug. 20, 2013). DOE received no comments related to electricity prices and used 2012 data for this final rule. For more information, see chapter 8 of the final rule TSD.

5. Energy Price Projections

To estimate the trends in energy prices, DOE used the price projections in *AEO2013*. To arrive at prices in future years, DOE multiplied current average prices by the projected annual average price changes in *AEO2013*. Because *AEO2013* projects prices to 2040, DOE used the average rate of change from 2030 to 2040 to estimate the price trend for electricity after 2040. In addition, the spreadsheet tools that DOE used to conduct the LCC and PBP analysis allow users to select price forecasts from the *AEO* low-growth, high-growth, and reference-case scenarios to estimate the sensitivity of the LCC and PBP to different energy price forecasts. 78 FR 51464, 51504 (Aug. 20, 2013). DOE received no comments related to energy price projections, and retained its approach for this final rule. For more information, see chapter 8 of the final rule TSD.

6. Replacement Costs

In the August 2013 NOPR, DOE addressed ballast and lamp replacements that occur within the LCC analysis period. Replacement costs include the labor and materials costs associated with replacing a ballast or lamp at the end of their lifetimes and are annualized across the years preceding and including the actual year in which equipment is replaced. For the LCC and PBP analysis, the analysis period corresponds with the fixture lifetime that is assumed to be longer than that of either the lamp or the ballast. For this reason, ballast and lamp prices and labor costs are included in the calculation of total installed costs.

DOE received numerous comments indicating that electronic HID lamp ballasts require additional voltage transient (surge) protection, in comparison to magnetic ballasts. High-voltage transients could result from, *e.g.*, lightning or wind effects and could shorten electronic ballast life in outdoor applications. (APPA, No. 51 at pp. 5–7; CA IOUs, No. 54 at p. 4; FP&L, Public Meeting Transcript, No. 48 at pp. 232–233; NEMA, No. 56 at pp. 16–17; ULT, No. 50 at p. 13; SCE&G, No. 49 at p. 1) NEMA stated that voltage transients are also a concern in indoor heavy industrial applications. (NEMA, No. 56 at p. 16) Several commenters also stated that it is not possible to determine when transient protection has reached its end of life, other than when it fails and causes a ballast failure in the process. (APPA, No. 51 at p. 5; NEMA, No. 56 at p. 16; Universal, No. 50 at p. 13) ASAP and GE suggested that transient-induced failures and maintenance should also be addressed in the LCC and PBP analysis. (ASAP, No. 62 at p. 5; GE, Public Meeting Transcript, No. 48 at p. 248)

For this final rule, DOE examined the potential effects of voltage transients on electronically ballasted fixtures in outdoor and heavy industrial indoor applications. As discussed previously in section V.C of this final rule, DOE's engineering analysis considers the additional cost of transient protection in determining the total cost for fixtures using electronic ballasts. DOE assumed that outdoor fixtures of all wattages could face transient-induced damage, and that industrial indoor fixtures in the 250 W and 400 W equipment classes were most susceptible to voltage transients, based on 2010 LMC data for average HID lamp wattages in indoor applications.

For outdoor fixtures, DOE examined data on the frequency and geographic distribution of lightning strikes from the National Lightning Safety Institute [40] and other sources to estimate additional surge protection and ballast replacements due to voltage transients. Lightning is more prevalent in the southern and lower midwestern regions of the United States, which leaves high concentrations of outdoor lighting fixtures, *e.g.*, in western and northeastern metropolitan areas, less affected by lightning. On a national level, DOE estimated that direct lightning strikes would be exceedingly rare—approximately 0.01 strikes per year on average, or approximately 1 direct strike per 100 years. DOE estimated that "near-strikes," which occur within a larger radius of the fixture and may be survivable by a protected electronic ballast, are also rare—approximately 0.04 strikes per year on average, or approximately 1 near-strike per 25 years. DOE, therefore, considered the probability of lightning-induced ballast replacements to be negligible for the average MHLF customer and did not consider this replacement event in its main LCC and PBP analysis. DOE expects that MHLF customers in lightning-prone areas will experience a higher probability of transient-induced ballast failures, and DOE estimated the related LCC and PBP effects in its subgroup analysis (see section V.H of this final rule).

For indoor applications, DOE assumed some 250 W and 400 W electronically ballasted fixtures were used in heavy industrial settings susceptible to voltage transients. The 2010 Lighting Market Characterization estimates that 434 W is the average wattage of metal halide lamps in the industrial sector. This means the vast majority of metal halide lamp fixtures in the industrial sector range between 250 W to 1000 W. The engineering analysis only proposed electronic ballasts for 250 W and 400 W light fixtures—thus those fixture types were the only types analyzed the LCC subgroup analysis. DOE's research determined that 60–80 percent of interior transients are

[39] Sweets-McGraw Hill Construction. *Sweets Electrical Cost Guide 2013*. 2012. Vista, CA.

[40] National Lightning Safety Institute. See *http://lightningsafety.com*.

generated by equipment (*e.g.*, elevators, machinery, air-conditioners) within the building. The magnitude of the transients generated ranged in size as did the frequency of the transients. Transient voltage surge suppressors (known mostly as TVSS) and/or other surge protection devices have become more common in industrial buildings. DOE found electronic fluorescent ballasts (although a different technology, an example of what can be accomplished) that manufacturers claimed could survive in industrial settings. DOE assumed that transients could reduce the life of electronic metal halide ballasts by 20 percent and thus modeled this reduction in the LCC subgroup analysis. DOE, therefore, considered the probability of transient-induced surge protection and ballast replacements to be negligible for the average MHLF customer and did not consider this replacement event in its main LCC and PBP analysis. DOE expects that some MHLF customers in heavy industrial indoor applications areas will experience a higher probability of transient-induced surge protection and ballast failures, and DOE estimated the related LCC and PBP effects in its subgroup analysis (see section V.H of this final rule).

For more information regarding replacement costs, see chapter 8 of the final rule TSD.

7. Equipment Lifetime

For the August 2013 NOPR, DOE defined equipment lifetime as the age (in hours in operation) when a fixture, ballast, or lamp is retired from service. The time period used for the LCC and PBP analysis in this rulemaking is the average lifetime of the baseline metal halide lamp fixture. For fixtures in all equipment classes, DOE assumed average lifetimes for indoor and outdoor fixtures of 20 and 25 years, respectively.

Metal halide lamp fixtures are operated by either magnetic or electronic ballasts. In the August 2013 NOPR, DOE assumed that magnetic ballasts last for 50,000 hours and electronic ballasts last for 40,000 hours. Similarly, MH lamp lifetimes vary by lamp technology and equipment class. DOE assumed that ballast and lamp lifetimes can vary due to both physical failure and economic factors (*e.g.*, early replacements due to retrofits); consequently, DOE accounted for variability in lifetimes in LCC and PBP via the Monte Carlo simulation, and in the shipments and NIA analyses by assuming a Weibull distribution for lifetimes to accommodate failures and replacements.[41] 78 FR 51464, 51504 (Aug. 20, 2013).

DOE received comments that its analysis unfairly penalized electronically ballasted designs by modeling an additional ballast replacement late in the fixture lifetime. For example, a customer with an electronically ballasted indoor fixture (20-year lifetime) would have to install a second replacement ballast approximately 2 years before retiring the fixture, which the commenters considered unrealistic. In comparison, a customer with a magnetically ballasted fixture would face only one ballast replacement, given the longer ballast lifetime. To more fairly model the late ballast replacements, the commenters suggested assigning a residual value to remaining ballast life at the end of the fixture's life. (ASAP, No. 62 at pp. 3–4; CA IOUs, No. 54 at pp. 4–5) DOE agrees with this approach, and included the residual value remaining in both lamps and ballasts in its LCC and PBP analysis. ASAP also suggested an alternative that uses a distribution of fixture lifetimes in the LCC and PBP analysis instead of a single average value. (ASAP, No. 62 at p. 4) DOE agrees with the use of a distribution of fixture lifetimes, which captures both early fixture failures (avoiding a second ballast replacement) and customers using fixtures beyond the average lifetimes (more fully using the second replacement ballast). For this final rule, DOE used a distribution of fixture, ballast, and lamp lifetimes as inputs to its LCC and PBP analysis.

For more information regarding equipment lifetimes, see chapter 8 of the final rule TSD.

8. Discount Rates

The discount rate is the rate at which future expenditures are discounted to estimate their present value. In this final rule, DOE estimated separate discount rates for commercial, industrial, and outdoor stationary applications. For all related customers, DOE estimated the cost of capital for commercial and industrial companies by examining both debt and equity capital, and DOE developed an appropriately weighted average of the cost to the company of equity and debt financing. For this final rule, DOE also developed a distribution of discount rates for each end-use sector from which the Monte Carlo simulation samples.

For each sector, DOE assembled data on debt interest rates and the cost of equity capital for representative firms that use metal halide lamp fixtures. DOE determined a distribution of the weighted-average cost of capital for each class of potential owners using data from the Damodaran online financial database.[42] The average discount rates, weighted by the shares of each rate value in the sectoral distributions, are 4.9 percent for commercial end users, 4.7 percent for industrial end users, and 3.4 percent for outdoor stationary end users.

For more information regarding discount rates, see chapter 8 of the final rule TSD.

9. Analysis Period Fixture Purchasing Events

DOE designed the LCC and PBP analysis for this rulemaking around scenarios where customers need to purchase a metal halide lamp fixture. The "event" that prompts the purchase of a new fixture (either a ballast failure or new construction/renovation) was assumed to influence the cost-effectiveness of the customer purchase decision. DOE assumed that a customer will replace a failed fixture with an identical fixture in the base case, or a new standards-compliant fixture with comparable light output in the standards case. DOE analyzed six representative equipment classes for fixtures and presented the results for each of these representative equipment classes by fixture purchasing event, which influenced the LCC and PBP results.

For more information regarding fixture purchasing events for the LCC analysis, see chapter 8 of the final rule TSD.

G. National Impact Analysis—National Energy Savings and Net Present Value Analysis

DOE's NIA assessed the national energy savings (NES) and the national net present value (NPV) of total customer costs and savings that would be expected to result from new or amended standards at specific efficiency levels.

DOE used a Microsoft Excel spreadsheet model to calculate the energy savings and the national customer costs and savings from each TSL. The TSD and other documentation for the rulemaking help explain the models and how to use them, enabling interested parties to review DOE's analyses by changing various input quantities within the spreadsheet.

[41] Weibull distribution is a probability density function; for more information, see *www.itl.nist.gov/div898/handbook/eda/section3/eda3668.htm.*

[42] The data are available at *pages.stern.nyu.edu/~adamodar.* (Last accessed August 21, 2013.)

DOE used the NIA spreadsheet to calculate the NES, and the NPV of costs and savings, based on the annual energy use and total installed cost data from the energy use and LCC analyses. DOE projected the energy savings, energy cost savings, equipment costs, and NPV of customer benefits for each equipment class for equipment sold from 2017 through 2046. The projections provided annual and cumulative values for all four output parameters.

DOE evaluated the impacts of new and amended standards for metal halide lamp fixtures by comparing base-case projections with standards-case projections. The base-case projections characterize energy use and customer costs for each equipment class in the absence of new or amended energy conservation standards. DOE compared these projections with projections characterizing the market for each equipment class if DOE adopted new or amended standards at specific energy efficiency levels (*i.e.*, the TSLs or standards cases) for that class. In characterizing the base and standards cases, DOE considered historical shipments, the mix of efficiencies sold in the absence of new standards, and how that mix may change over time. Additional information about the NIA spreadsheet is in the final rule TSD chapter 11.

Table V.8 summarizes the approach and data DOE used to derive the inputs to the NES and NPV analyses for the August 2013 NOPR, as well as the changes to the analyses for the final rule. A discussion of selected inputs and changes follows. See chapter 11 of the final rule TSD for further details.

TABLE V.8—APPROACH AND DATA USED FOR NATIONAL ENERGY SAVINGS AND CUSTOMER NET PRESENT VALUE ANALYSES

Inputs	Proposed rule	Changes for the final rule
Shipments	Developed annual shipments from shipments model	See Table V.9.
Annual Energy Consumption per Unit	Established in the energy use analysis (NOPR TSD chapter 7)	See section V.E.
Rebound Effect	0%	No change.
Electricity Price Forecast	*AEO2013*	*No change.*
Energy Site-to-Source Conversion Factor	Used annually variable site kWh to source Btu conversion factor	*No change.*
Discount Rate	3% and 7% real	No change.
Present Year	2013	No change.

1. Shipments

Equipment shipments are an important component of any estimate of the future impact of a standard. Using a three-step process, DOE developed the shipments portion of the NIA spreadsheet, a model that uses historical data as a basis for projecting future fixture shipments. First, DOE used U.S. Census Bureau fixture shipment data, NEMA lamp shipment data, and NEMA ballast sales trends to estimate historical shipments of each fixture type analyzed. Second, DOE estimated an installed stock for each fixture in 2017 based on the average service lifetime of each fixture type. Third, DOE developed annual shipment projections for 2017–2046 by modeling fixture purchasing events, such as replacement and new construction, and applying growth rate, replacement rate, and alternative technologies penetration rate assumptions. For details on the shipments analysis, see chapter 10 of the final rule TSD.

TABLE V.9—APPROACH AND DATA USED FOR THE SHIPMENTS ANALYSIS

Inputs	Proposed rule	Changes for the final rule
Historical Shipments	Used historical HID fixture and lamp shipments to develop shipments for MH fixtures.	Revised historical MH fixture shipments based on updated NEMA MH ballast shipment trends.
Fixture Stock	Based projections on the shipments that survive up to a given date; assumed Weibull lifetime distribution.	No change.
Growth	Adjusted based on fixture market	No change.
Base Case Scenarios	Developed "low" and "high" shipments scenarios	Revised "low" and "high" shipments scenarios based on revised historical MH fixture shipments.
Standards Case Scenarios	Analyzed Roll-up only	No change.

a. Historical Shipments

For the August 2013 NOPR, DOE reviewed U.S. Census Bureau data from 1993 to 2001 for metal halide lamp fixtures.[43] DOE compared the MHLF census data to NEMA data for historical metal halide lamp shipments from 1990 to 2008 taken from DOE's final determination for HID lamps published on July 1, 2010. 75 FR 37975. DOE found a correlation between metal halide lamp fixture and metal halide lamp shipments. From 1993 to 2001, the number of MHLF shipments on average represented 37 percent of the amount of lamp shipments, with a standard deviation of 3 percent. Using this relationship, DOE multiplied all of the metal halide lamp shipments from 1990 to 2010 by 37 percent to estimate the historical shipments of metal halide lamp fixtures. DOE assumed that shipments for metal halide lamp fixtures would peak somewhere between 2010 and 2015, and generally decline thereafter. 78 FR 51464, 51506 (Aug. 20, 2013).

DOE received multiple comments indicating that its shipments analysis significantly underestimated the rate of decline in the MHLF market, and thereby overestimated total MHLF shipments. (APPA, No. 51 at p. 2; NEMA, No. 56 at pp. 2, 4, 22; ULT, No. 50 at p. 15) NEMA presented new MH ballast sales trend graphs at the NOPR public meeting, suggesting a much

[43] U.S. Census Bureau. *Manufacturing, Mining, and Construction Statistics.* Current Industrial Reports, Fluorescent Lamp Ballasts, MQ335C. 2008. (Last accessed October 28, 2013). *www.census.gov/mcd/.*

steeper decline in fixture shipments from 2008 to 2013 than assumed in the August 2013 NOPR. (NEMA, No. 44 at p. 15) For this final rule, DOE retained its peak in fixture shipments, and revised its trend for subsequent historical shipments to approximate the new sales trend information provided by NEMA. As a result, total estimated MHLF shipments for 2013 were approximately 31 percent lower than in the August 2013 NOPR. By extension, DOE also revised its projected base case shipments downward, as discussed in section V.G.1.c of this final rule.

b. Fixture Stock Projections

In the August 2013 NOPR shipments analysis, DOE calculated the installed fixture stock using estimated historical fixture shipments and its projected shipments for future years. DOE estimated the installed stock during the analysis period by using fixture shipments and calculating how many will survive up to a given year based on a Weibull lifetime distribution for each fixture type. 78 FR 51464, 51506 (Aug. 20, 2013). DOE received no comments on the August 2013 NOPR regarding its fixture stock projection method and retained this approach for this final rule.

c. Base Case Shipment Scenarios

For the August 2013 NOPR, DOE assumed that shipments for MHLFs peaked somewhere between 2010 and 2015. For projected fixture shipments in the "low" and "high" shipment scenarios, DOE projected a decline that fell back to the levels in 2000 and 2006, respectively.[44] 78 FR 51464, 51506 (Aug. 20, 2013). As discussed previously, several commenters stated that DOE overestimated total MHLF shipments in its NOPR analysis. (APPA, No. 51 at p. 2; NEMA, No. 56 at pp. 2, 4, 22; ULT, No. 50 at p. 15) For this final rule, DOE used new MH ballast sales trend information provided by NEMA to revise its historical fixture shipments, resulting in significantly lower shipment estimates for 2008 to 2013. As a result, DOE's projected fixture shipments through 2047 were also significantly lower; *for example,* the "low" scenario shipments for 2020 were 31 percent lower than the corresponding NOPR estimate and declined to approximately pre-1990 levels by the end of the shipments analysis period.

d. Standards-Case Efficiency Scenarios

Several of the inputs for determining NES (*e.g.,* the annual energy consumption per unit) and NPV (*e.g.,* the total annual installed cost and the total annual operating cost savings) depend on equipment efficiency. For the August 2013 NOPR, DOE used a "Roll-up" shipment efficiency scenario, which is a standards case in which all equipment efficiencies in the base case that do not meet the standard would "roll up" to the lowest level that can meet the new standard level. Equipment efficiencies in the base case above the standard level are unaffected in the Roll-up scenario, as these customers are assumed to continue to purchase the same base-case fixtures. The Roll-up scenario characterizes customers primarily driven by the first cost of the analyzed equipment, which DOE believes more accurately characterizes the metal halide lamp fixture marketplace. 78 FR 51464, 51506 (Aug. 20, 2013).

NEMA and ULT commented on the August 2013 NOPR, stating that setting a standard for 150 W fixtures that requires electronic ballasts will steer customers to higher wattage, magnetically ballasted fixtures. (NEMA, Public Meeting Transcript, No. 48 at pp. 33–34; NEMA, No. 44 at p. 9; NEMA, No. 56 at p. 24; ULT, Public Meeting Transcript, No. 48 at pp. 144–145; ULT, No. 50 at p. 2)

DOE agrees that there is some possibility of a shift between the technologies. The ballast types play a role in the decision, but so do initial costs, life-cycle costs, and utility features of the light source. DOE assume that customer would not opt for the 175 W magnetically ballasted fixture if the 150 W light fixture is cheaper. DOE's analysis has the 175 W metal halide lamp fixture at the baseline and efficiency levels 1–3 to be greater than the 150 W metal halide lamp fixture at the baseline and efficiency levels 1–3. Therefore, DOE assumes that only if a standard that were set requiring efficiency level 4 would customers chose to install 175 W metal halide lamp fixtures. In this shift scenario, DOE did not assume an overwhelming number of customers would shift to 175 W because the economics and utility features between the two options were similar. Because the options were so similar, there was no an overwhelming reason for customers to make large shifts to the 175 W metal halide lamp fixture as a result of a standard requiring electronic ballasts for 150 W metal halide lamp fixtures.

Similarly, DOE modeled a shift of customers migrating from 1000 W probe-start fixtures to either 875 W pulse-start or 1000 W pulse-start fixtures as a result of the design standard being part of this rule. In order to examine the market shift that would be expected to occur under a design standard for the 500 W–1000 W equipment class, DOE developed an econometric-based consumer choice model to estimate the relative fraction of 1000 W probe-start fixture customers who migrate to 1000 W pulse-start and 875 W pulse-start fixtures. The consumer choice model was based on a conditional logit model to establish consumer preference between these two options, based on economic parameters, coupled with a market diffusion curve to estimate the rapidity of movement in the market toward the consumer preference predicted by the logit model. Data underlying the consumer choice model reflected that for commercial and industrial lighting purchasers as presented in DOE's General Service Fluorescent Lamps preliminary analysis technical support document.[45] DOE estimated that approximately 27 percent of those customers using 1000 W probe-start fixtures in the base case shipment forecast would shift to 875 W pulse-start fixtures and the remaining 73 percent of 1000 W probe-start customers would migrate to 1000 W pulse-start fixtures. These market shifts were used in the shipments estimates underlying the calculation of the design standard benefits in the NIA.

DOE also received comments on the August 2013 NOPR stating that additional costs resulting from potential standards could increase the rate at which MHLF customers migrate to other lighting technologies. (APPA, No. 51 at pp. 2–3; NEMA, No. 56 at p. 23; ULT, No. 50 at p. 15) NEMA noted that costs for many fixture types had already increased to meet recent new National Electrical Code requirements. (NEMA, No. 56 at p. 23) NEMA and ULT observed that applications requiring high lumen output and high-temperature operating environments still favor metal halide lamp fixtures, however. (NEMA, No. 56 at p. 22; ULT, No. 50 at p. 15) DOE believes that its

[44] The August 2013 NOPR text at 78 FR 51463, 51506 (August 20, 2013) incorrectly indicated that fixture shipments in the "high" scenario in 2040 roughly equaled the shipments in 2006. Several commenters stated that the declining MHLF market would not return to 2006 shipment levels. (APPA, No. 51 at p. 2; NEMA, No. 56 at p. 4) DOE's actual modeled fixture shipments for 2040 were roughly equal to pre-2000 shipments, significantly lower than the 2006 peak.

[45] U.S. Department of Energy—Office of Energy Efficiency and Renewable Energy. Energy Conservation Program for Consumer Products: Preliminary Technical Support Document: Energy Efficiency Standards for Consumer Products: General Service Fluorescent Lamps and Incandescent Reflector Lamps. February 2013. Washington, DC. *http://www.regulations.gov/#!documentDetail;D=EERE-2011-BT-STD-0006-0022.*

revised base case shipments (that incorporate new NEMA sales trend information) capture the main effect of migration to other lighting technologies, and illustrate a significant decrease in total MHLF shipments compared to the NOPR analysis. DOE reserved the standards-case shipments scenario to characterize the purchasing behaviors of remaining MHLF customers, and retained its Roll-up approach for this final rule.

2. Site-to-Source Energy Conversion

To estimate the national energy savings expected from appliance standards, DOE uses a multiplicative factor to convert site energy consumption into primary or source energy consumption (the energy required to convert and deliver the site energy). These conversion factors account for the energy used at power plants to generate electricity and losses in transmission and distribution, as well as for natural gas losses from pipeline leakage and energy used for pumping. For electricity, the conversion factors vary over time due to projected changes in generation sources (*i.e.*, the types of power plants projected to provide electricity to the country). The factors that DOE developed are marginal values, which represent the response of the system to an incremental decrease in consumption associated with appliance standards.

For the August 2013 NOPR, DOE used the annually variable site-to-source conversion factors based on the version of NEMS that corresponds to *AEO2013*, which provided energy forecasts through 2035. For 2036–2044, DOE used conversion factors that remain constant at the 2035 values. 78 FR 51464, 51506 (Aug. 20, 2013). DOE received no comments regarding site-to-source conversion factors, and retained its approach for today's final rule.

DOE has historically presented NES in terms of primary energy savings. In response to the recommendations of a committee on "Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards" appointed by the National Academy of Science, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (August 18, 2011) While DOE stated in that notice that it intended to use the Greenhouse Gases, Regulated Emissions, and Energy Use in Transportation (GREET) model to conduct the analysis, it also said it would review alternative methods, including the use of NEMS. After evaluating both models and the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in the **Federal Register** in which DOE explained its determination that NEMS is a more appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (August 17, 2012). DOE received one comment, which was supportive of the use of NEMS for DOE's FFC analysis.[46]

The approach used for today's final rule, and the FFC multipliers that were applied, are described in appendix 11B of the final rule TSD. NES results are presented in both primary and FFC savings in section VII.B.3.a.

H. Customer Subgroup Analysis

The life-cycle cost subgroup analysis evaluates impacts of standards on identifiable groups, such as different customer populations or business types that may be disproportionately affected by any national energy conservation standard level. For the August 2013 NOPR, DOE estimated LCC savings and payback periods for three subgroups: Utilities, transportation facility owners, and warehouse owners. These three subgroups were distinguished from average MHLF customers by higher maintenance costs (utilities), higher operating hours (transportation facility owners), and lower operating hours (warehouse owners). 78 FR 51464, 51507 (Aug. 20, 2013).

Several utilities commented that DOE incorrectly assigned the same retail electricity rates to all three subgroups, when utilities would instead pay lower wholesale rates, resulting in lower energy cost savings and longer payback periods. (APPA, No. 51 at pp. 8–9; EEI, No. 53 at p. 4; NRECA, No. 61 at p. 2) DOE agrees with this distinction, and DOE referenced EIA wholesale electricity prices[47] for the utility subgroup in its final rule analysis. As discussed previously in section V.F.6 of this final rule, DOE is also evaluating two new customer subgroups for transient-prone fixtures in outdoor and heavy industrial indoor applications. DOE assumed that owners of transient-prone outdoor fixtures would face shortened surge protection and electronic ballast lifetimes because of lightning-induced voltage transients, resulting in a 15 percent shorter electronic ballast life requiring more frequent electronic ballast and surge protection device replacements during the fixture lifetime. For indoor fixtures, DOE assumed that fixture owners in heavy industrial environments would face shortened surge protection and electronic ballast lifetimes because of voltage transients, resulting in a 20% shorter electronic ballast life requiring more frequent electronic ballast and surge protection device replacements during the fixture lifetime.

For more information regarding the customer subgroup analysis, see chapter 12 of the final rule TSD.

I. Manufacturer Impact Analysis

DOE conducted an MIA to estimate the financial impact of new and amended energy conservation standards on manufacturers of MHLFs and ballasts, and to estimate the impact of new and amended standards on employment and manufacturing capacity. The quantitative aspect of the MIA relies on the GRIM, an industry cash-flow model customized for MHLFs and ballasts covered in this rulemaking. The GRIM is used to calculate INPV, which is the key MIA output. In its analysis, DOE used the GRIM to calculate cash flows using standard accounting principles and to compare the difference in INPV between the base case and various TSLs (the standards cases). The difference in INPV between the base and standards cases represents the financial impact of new and amended MHLF standards on MHLF and ballast manufacturers. DOE employed different assumptions about markups and future shipments to produce ranges of results that represent the uncertainty about how the MHLF and ballast industries will respond to energy conservation standards.

In the MIA, DOE typically groups its estimates of manufacturer impacts by the major equipment types that are produced by the same manufacturers. The covered equipment in today's rulemaking is MHLFs; however, by requiring particular MH ballast efficiencies in this regulation, MH ballast manufacturers will also be affected by new and amended MHLF standards. The MHLF and ballast markets are served by separate groups of manufacturers. DOE therefore presents impacts on MHLF manufacturers and MH ballast manufacturers separately.

DOE outlined its complete methodology for the MIA in the previously published NOPR. The complete MIA is presented in chapter 13 of this final rule TSD.

1. Manufacturer Production Costs

Manufacturing higher-efficiency equipment is typically more expensive than manufacturing baseline equipment

[46] Docket ID: EERE–2010–BT–NOA–0028, comment by Kirk Lundblade.

[47] See *www.eia.gov/electricity/wholesale/* (Last accessed December 2013).

due to the need for more costly components. The resulting changes in the MPCs of the analyzed equipment can affect the revenues, gross margins, and cash flows of manufacturers. DOE strives to accurately model the potential changes in these equipment costs, as they are a key input for the GRIM and DOE's overall analysis. For the final rule, DOE updated the MHLF and some ballast MPCs based on stakeholder comments. For a complete description of the changes made to the MPCs see section V.C.12 of this final rule.

2. Shipment Projections

Changes in sales volumes and efficiency distribution of equipment over time can significantly affect manufacturer finances. The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of shipments by efficiency level. For the final rule, DOE reduced the number of shipments of MHLFs in both the low- and high-shipment scenarios based on stakeholder comments. For the MIA, the GRIM uses the NIA's annual shipment projections from the base year, 2014, to 2046, which is the end of the analysis period. For a complete description of the changes made to the shipment analysis see section V.G.1 of this final rule.

3. Markup Scenarios

For the MIA, DOE modeled two standards case markup scenarios to represent the uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of new and amended energy conservation standards: (1) A flat, or preservation of gross margin, markup scenario and (2) a preservation of operating profit markup scenario. These scenarios lead to different markup values, which when applied to the inputted MPCs, result in varying revenue and cash-flow impacts.

For the final rule, DOE did not alter the markup scenarios, values, or methodology used in the NOPR analysis.

4. Production and Capital Conversion Costs

New and amended energy conservation standards will cause manufacturers to incur one-time conversion costs to bring their production facilities and equipment designs into compliance. For the MIA, DOE classified these one-time conversion costs into two major groups: (1) Product conversion costs and (2) capital conversion costs. Product conversion costs are one-time investments in research, development, testing, marketing, and other non-capitalized costs necessary to make equipment designs comply with the new and amended standards. Capital conversion costs are one-time investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new equipment designs can be fabricated and assembled. DOE created separate conversion costs for MHLF and ballast manufacturers.

In response to the NOPR, Acuity stated they believed the conversion costs for fixture manufacturers seemed surprisingly low. (Acuity, Public Meeting Transcript, No. 48 at p. 285) DOE assumed that there would not be any capital conversion costs for fixture manufacturers at efficiency levels requiring more efficient magnetic ballasts. This is based on DOE's assumption in the engineering analysis that the size of the magnetic ballast would not need to be increased at those efficiency levels and therefore, fixture manufacturers would not need to redesign their MHLFs to be compatible with the higher efficiency magnetic ballasts. Fixture manufacturers would, however, incur product conversion costs at efficiency levels requiring magnetic ballasts. Higher ballast efficiency levels would require fixture manufacturers to re-test and re-certify fixtures with ballasts that were redesigned to meet standards. DOE believes that there would be both product conversion costs, as well as capital conversion costs, for fixture manufacturers at all efficiency levels requiring electronic ballasts since fixture manufacturers producing MHLFs containing magnetic ballasts would need to redesign their fixture production process.

Several manufacturers stated there would be significant conversion costs to comply with the MHLF standards proposed in the NOPR. Cooper, for example stated that they would have to make substantial investments to comply with the standards proposed in the NOPR. (Cooper, Public Meeting Transcript, No. 48 at p. 58) ULT expressed concern that complying with the proposed standards would consume significant company time and resources. They commented that from a design cycle standpoint, one fixture could take eight to 12 months to redesign and test, which includes design validation testing, UL testing, and life-cycle testing. (ULT, Public Meeting Transcript, No. 48 at p. 201) DOE acknowledges that manufacturers would have to make investments to comply with MHLF standards. As part of the MIA, DOE attempts to quantify the time and monetary expenditures that would comprise the capital and product conversion costs, which MHLF and ballast manufacturers would need to incur to convert all their equipment to meet the standards. These conversion cost estimates were based on DOE's research and modified based on manufacturer feedback during interviews.

DOE modified the capital conversion costs for the final rule based on the reduction in shipments modeled in the final rule shipments analysis. Consequently, DOE reduced the capital conversion costs proportionally to the reduction in shipments of the final rule, since capital conversion costs are correlated to the shipment volume in the year standards require compliance. DOE did not alter the product conversion costs since these costs are correlated with the number of product designs impacted by standards, not necessarily the shipment volume in the year standards require compliance.

5. Other Comments From Interested Parties

During the NOPR public meeting and comment period, interested parties commented on the assumptions, methodology, and results of the NOPR MIA. DOE received comments about the compliance period, alternative technologies, the opportunity cost of investments, the replacement ballast market, and potential impact on MH lamp manufacturers. These comments are addressed below.

a. Compliance Period

NEMA stated that based on its analysis, a three-year compliance period would be inadequate for the extensive R&D effort that MHLF and ballast manufacturers would have to undergo in order to redesign all equipment to be compliant with the efficiency levels proposed in the NOPR. NEMA stated that in their analysis, they found that manufacturers would face significant technical obstacles when trying to produce high volumes of compliant MHLFs and ballasts due to the challenging nature of processing higher-grade materials, such as M6 steel. NEMA does not believe that lighting manufacturers are willing to dedicate enough resources to MHLF and ballast technology to be able to redesign all wattages during a three-year time period. (NEMA, No. 56 at p. 3) While DOE acknowledges there are difficulties and costs associated with manufacturing higher efficiency products, all efficiency levels analyzed in DOE's engineering analysis, including max tech, are

technologically feasible to manufacture. For a complete description of MHLFs and ballasts and analyzed in the engineering analysis see section V.C of this final rule.

NEMA also commented that the MHLF NOPR proposed expanding the scope of covered equipment to include wattage ranges previously not covered by the standards prescribed in EISA 2007, as well as eliminating exemptions for certain equipment that were granted by EISA 2007. According to NEMA, the number of MHLFs impacted would be significant and bringing them into compliance would be time-consuming and costly. NEMA listed some of the most significant compliance obstacles that manufacturers would face including: Evaluating ballast performance to identify compliant ballasts; determining if ballasts in fixtures need to be replaced; modifying order and quotation systems; obtaining the test data for CCE; educating manufacturing staff; educating customers; and managing order backlogs. NEMA believes that managing these logistics would divert limited resources within lighting divisions and would prevent manufacturers from focusing on developing and selling more efficient lighting technology, such as LEDs. According to NEMA, the proposed standards would delay the market transition to technologies that are more efficient than those established by this rulemaking. (NEMA, No. 56 at p. 20)

During the NOPR public meeting, NEMA further emphasized the complex logistics manufacturers would face in complying with new and amended energy conservation standards. NEMA stated that a large amount of equipment would have to be redesigned and several sales channels would be impacted if DOE expanded the scope of covered MHLFs beyond what was included in EISA 2007. (NEMA, Public Meeting Transcript, No. 48 at pp. 19–20) According to NEMA, manufacturers would have to employ significant company resources to educate internal staff, such as marketing and sales representatives, about new equipment available for purchase. Time and money would also have to be spent updating IT systems due to changes in order processing and inventory management software. (NEMA, Public Meeting Transcript, No. 48 at p. 22)

NEMA further argued that manufacturers would have to use company resources to educate their customers about redesigned compliant equipment. For fixture manufacturers, customers include OEMs, distributors, contractors, designers, home centers, and showrooms. Manufacturers would have to modify marketing materials and manage orders and contracts which might extend one to two years into the future. According to NEMA, managing these contracts would be complicated, as the prices and performances of the MHLFs are generally guaranteed and would change due to standards. (NEMA, Public Meeting Transcript, No. 48 at p. 26) Ballast manufacturers also often have one or two-year contracts with their customers, who agree to buy ballasts that achieve particular performance levels for an agreed upon price. Ballast manufacturers would have to renegotiate these contracts, which would be difficult because prices and ballast performances would change due to standards. (NEMA, Public Meeting Transcript, No. 48 at p. 23)

NEMA also stated that fixture manufacturers would not be able to start preparing for energy conservation standards until ballast manufacturers had completed their redesign and compliance efforts. Fixture manufacturers would have to assess whether redesigned ballasts were the same form and size and whether they had the same thermal characteristics before they would be able to begin redesigning fixtures. According to NEMA, if a particular ballast needed to be redesigned, that could mean dozens, if not hundreds, of unique fixtures using that particular ballast would also need to be redesigned. NEMA stated any change in a ballast's form or thermal characteristics would require a tremendous redesign effort for fixture manufacturers. (NEMA, Public Meeting Transcript, No. 48 at p. 25)

NEMA further commented that MHLFs and ballasts would also have to go through electrical, safety, thermal, and photometric testing, all of which would consume manufacturers' time and resources. NEMA expressed concern that testing of the new and modified ballasts and fixtures would take a significant amount of time and would further complicate manufacturers' efforts to abide by the three-year compliance period. NEMA pointed out that when the DOE CCE rule went into effect, manufacturers took six months to obtain accurate samples for certification. Manufacturers would have to redesign and test modified ballasts and fixtures before even beginning to collect samples for the CCE rule. NEMA argued that this would be difficult to achieve within the three-year compliance period. (NEMA, Public Meeting Transcript, No. 48 at p. 22) NEMA also questioned whether UL could handle the volume of testing that would be necessary to comply with standards in such a short period of time since all redesigned MHLFs and ballasts would need to be certified. (NEMA, Public Meeting Transcript, No. 48 at p. 26)

DOE acknowledges that new and amended energy conservation standards will require MHLF and ballast manufacturers to undergo changes to their production processes, modify existing equipment, develop new models, and make a series of complex logistical decisions. In the NOPR, DOE assumed ballast and fixture manufacturers must comply with standards as of January 1, 2015. However, as described in section VI.C, DOE has revised the compliance date in the final rule to be consistent with the three-year time frame specified in EISA 2007. DOE assumes a three-year compliance period when estimating all capital and product conversion costs, which DOE included as potential burdens when selecting standards for MHLFs.

b. Alternative Technologies

DOE recognizes that there are alternative lighting technologies that can be used in the same applications as MHLFs and that MHLF shipments are on the decline. Lighting manufacturers, for example are heavily investing in R&D for LEDs, an advanced and highly efficient lighting technology for which demand is growing rapidly. LED technology has matured to the point that it can be used in a number of applications in which MHLFs are typically used, predominantly at lower wattages. However at higher wattages, it is more difficult for customers to switch from MH to LED.

At the NOPR public meeting, Philips pointed out that a majority of R&D resources within the lighting industry have already been transferred to LEDs and away from traditional lighting technologies. (Philips, Public Meeting Transcript, No. 48 at p. 50) ULT stated that by creating new standards for a technology with declining market share, DOE is hindering this trend, as manufacturers will have to divert resources away from developing more advanced and efficient technologies to convert their metal halide product lines. (ULT, Public Meeting Transcript, No. 48 at p. 61) Acuity noted, however, that in the higher-wattage applications, LED technology has not yet developed a high-intensity lighting solution, and therefore the market will be forced to continue to develop MH lamps for those applications. (Acuity, Public Meeting Transcript, No. 48 at p. 24)

APPA, NRECA, and EEI all noted that due to market conditions and the

existence of other lighting technologies, manufacturers may have no incentive to make replacement ballasts for existing MHLFs. (APPA, No. 51 at p. 7; NRECA, No. 61 at p. 2; EEI, No. 53 at p. 3) APPA pointed out that MH ballast production has been declining since 2008 and that manufacturers may decide to halt the production of replacement ballasts to focus on LEDs. APPA argued that if replacement ballasts became commercially unavailable, the original intent of the rule, which was not to force the implementation of new fixtures, would be lost. (APPA, No. 51 at p. 7) NEEA argued that to avoid this problem, regulations are needed for LEDs so that manufacturers would have incentive to perform research and development on MHLFs to make them more efficient. (NEEA, Public Meeting Transcript, No. 48 at p. 53)

DOE acknowledges that the MHLF market is currently in decline and has modeled this decline into its projections of future MHLF and ballast shipments. Any effects of increased R&D of technologies not covered by this rulemaking and the market penetration of those technologies into the MHLF market are discussed in the following section of the MIA (V.I.5.c) DOE agrees that there are a number of applications in which LED cannot provide equivalent lumen output to MHLF light levels and that there will be a continued market for this equipment. DOE expects that even with the standards adopted by this final rule there will be a market for manufacturers to make replacement ballasts.

c. Opportunity Cost of Investments

Several manufacturers commented that developing MHLFs to meet energy conservation standards would have opportunity costs. NEMA argued that diverting resources to convert MHLFs and ballasts to comply with new and amended standards would negatively impact the lighting market by delaying the introduction of products with potentially higher efficiency, better utility, and more responsive controls. (NEMA, No. 56 at p. 24) Musco Lighting commented that the proposed standard requiring pulse-start lamps would divert critical R&D resources to attempt to develop a technology that does not exist and to this point has not been determined as commercially achievable. Musco Lighting stated R&D resources in the lighting industry should remain focused on technologies that have significant opportunities for energy reduction, such as LEDs. Musco Lighting believes the proposed MHLF standards would not achieve significant energy savings and would potentially hold back substantial lighting efficiency gains by diverting resources. (Musco Lighting, No. 55 at p. 3)

Most manufacturers agreed that LEDs are the future of the lighting industry, and therefore are primarily focusing R&D resources on this technology as opposed to MH technology. As a result, NEMA pointed out that lighting manufacturers are working with fewer human resources dedicated to MH than they were when they first had to come into compliance with EISA 2007 MH standards. Meeting those standards was very complicated for manufacturers even with the more abundant resources that were available. It will be difficult for companies to simultaneously develop LEDs and upgrade MHLFs and ballasts (NEMA, Public Meeting Transcript, No. 48 at p. 20)

ULT pointed out that while LEDs are growing in market share, they are still not mature enough to work well in all applications; however, manufacturers are getting closer to achieving this through R&D. According to ULT, lighting manufacturers are working on developing fixtures that are designed to remove heat, keep water out, and help protect against surges to allow the use of LEDs in all fixtures. ULT believes that MHLF standards requiring manufacturers to spend over a year designing, testing, and validating MHLFs and ballasts would slow the integration of LEDs into the market and force manufacturers to work on lighting technologies that may not be in the market in the next five to 10 years. (ULT, No. 50 at p. 16–17) NEMA commented that if manufacturers chose to convert their MH equipment to the proposed efficiency levels, the higher priced MHLFs could cause customers to shift to LEDs anyway, which would mean that manufacturers would not recoup the cost of investment into MHLFs. (NEMA, Public Meeting Transcript, No. 48 at p. 150) Several manufacturers and NEMA said that these considerations could cause some fixture and ballast manufacturers to exit the MH market. (NEMA, Public Meeting Transcript, No. 48. 283)

NEMA argued that manufacturers may choose to exit the market due to the fact that the proposed standards could have severe impacts on manufacturers. They noted that in DOE's NOPR analysis, MH ballast manufacturers would need to invest up to 29 million dollars at the proposed TSL and this could result in up to a 25 percent loss of base case INPV. According to NEMA, the impacts will be more severe than DOE projected in the NOPR because NEMA believes that shipments of MHLFs and ballasts will decline much faster than DOE projected. NEMA argued that the rapidly declining MH market makes it difficult for manufacturers to justify the significant investments necessary to comply with MHLF standards. (NEMA, No. 56 at p. 23) DOE has adjusted the projected volume of shipments based on stakeholder feedback. In the final rule shipment analysis, there is a sharper decline in MHLF shipments as suggested by NEMA's comment. For a complete description of the changes made to the shipment analysis see section V.G.1 of this final rule.

DOE recognizes the opportunity cost associated with any investment, and agrees that manufacturers would need to spend capital and company resources to meet today's standards that they would not have to spend in the absence of standards. As a result, manufacturers must determine the extent to which they will balance investment in the MH market with investment in emerging technologies, such as LEDs. These companies will have to weigh tradeoffs between deferring investments and deploying additional capital. DOE includes the costs of meeting today's standard in the conversion costs portion of the MIA.

d. Replacement Ballast Market

As noted in the scope of coverage section, this rulemaking covers new MHLFs. Even though the metric being regulated is ballast efficiency, the standards set in this rulemaking only apply to ballasts sold with new fixtures. Ballasts sold separately, to be used as replacement ballasts for existing fixtures, are not required to comply with these standards.

There was some concern among stakeholders that manufacturers might not choose to manufacture similar wattage ballasts at multiple efficiency levels due to lack of economic viability. ULT and Cooper both commented that the proposed standard for new MHLFs would affect all MH ballasts and not just new MHLFs because it is economically infeasible to maintain two different ballast product lines—one that services the replacement market that would not be subject to standards and another that services the new MHLF market that would be subject to standards. (ULT, Public Meeting Transcript, No. 48 at p. 65–66; Cooper, Public Meeting Transcript, No. 48 at p. 67) NEEA argued that while this was probably true, as long as there is a market for replacement MH ballasts, some companies would manufacture those replacement ballasts to fulfill that market. According to NEEA, a manufacturer could continue their current MH ballast production line

which would only service the replacement MH ballast market and not manufacture ballasts for new MHLFs. (NEEA, Public Meeting Transcript, No. 48 at p. 72) ULT responded by commenting that manufacturers are not going to want to redesign and manufacture two production lines for MH ballasts which would increase their inventory and carrying costs for MH ballasts and rather will continue to focus on solid state lighting. ULT believes this could open up the replacement ballasts market to offshore MH ballast manufacturers and result in an increase in products that will have quality and warranty problems, which is bad for end-users. (ULT, Public Meeting Transcript, No. 48 at p. 73)

Also several organizations commented on the impact of MHLF standards on the portfolio of ballasts available for the replacement market. APPA requested confirmation that the standards proposed in the NOPR would not eliminate the production of replacement ballasts for existing and future MHLFs. (APPA, No. 51 at p. 1) NEMA, ULT, and APPA stated manufacturers could not be expected to maintain product lines for both new fixture ballasts and for the replacement or repair of old fixtures. Therefore, customers with MHLFs currently installed might be left with stranded assets. However, NEMA, ULT, and APPA noted that if standards do not force customers to switch to electronic ballasts or magnetic ballasts to incur physical changes, the market could continue to be adequately serviced by manufacturers. (NEMA, No. 56 at pp. 10, 24; ULT, No. 50 at pp. 17–18; APPA, No. 51 at p. 8) GE noted that if the standard were to require larger ballasts, it would mean having no direct replacement for the installed base, especially in a situation such as a natural disaster, where the majority of lighting in a subdivision would need to be replaced. (GE, Public Meeting Transcript, No. 48 at p. 89) Conversely, the Joint Comment stated that there will always be a market for these replacement ballasts, regardless of the efficiency requirements, and that it would be a business decision whether manufacturers would want to fill that niche market. (Joint Comment, No. 62 at p. 7)

DOE's market analysis found that several of the largest manufacturers of MH ballasts responded to the standards mandated by EISA 2007 for 150 W–500 W ballasts sold with new fixtures by offering ballasts with efficiencies that comply with EISA 2007 standard levels, and replacement ballasts with efficiencies that do not comply with EISA 2007, at the same wattages. While DOE predicts a similar response to the standards adopted in this final rule, the financial viability of offering ballasts that fall above and below these standards will be a business decision for each manufacturer. For the MIA, DOE includes the costs of upgrading MH ballast production for new MHLFs (and not upgrading replacement ballasts) to meet the standards in its analysis and any other course of action would be a business decision made by manufacturers which is not modeled by DOE.

e. Potential Impact on Metal Halide Lamp Manufacturers

Philips commented that there could be a negative impact on MH lamp manufacturers due to MHLF standards. Philips stated as the cost of MHLFs increase due to standards more people are going to purchase LEDs and as a result, the volume of MHLFs and MH lamps will decrease. Therefore, Philips believes that DOE should take into account costs imposed on MH lamp manufacturers associated with MHLF standards. (Philips, Public Meeting Transcript, No. 48 at p. 277) DOE recognizes that LEDs are continuing to capture more and more of the lighting markets serviced by MHLFs and accounts for this shift to LEDs in the shipment analysis for this rulemaking. DOE does not believe that MHLF standards will hasten this shift to LEDs, as LEDs are not appropriate substitutes for all MHLFs given the large lumen output of the higher wattage MHLFs. Therefore, this market shift to LEDs is captured in the base case shipment scenario and is not modeled as a standards-induced market shift.

6. Manufacturer Interviews

DOE interviewed manufacturers representing more than 65 percent of MHLF sales and 90 percent of MH ballast sales. The NOPR interviews were in addition to the preliminary interviews DOE conducted as part of the interim analysis. DOE outlined the key issues for the rulemaking for manufacturers in the NOPR. DOE considered the information received during these interviews in the development of the NOPR and this final rule. Comments on the NOPR regarding the impact of standards on manufacturers were discussed in the preceding sections. DOE did not conduct interviews with manufacturers between the publication of the NOPR and this final rule.

J. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a standard. Employment impacts consist of direct and indirect impacts. Direct employment impacts are any changes in the number of employees working for manufacturers of the equipment subject to standards, their suppliers, and related service firms. The MIA addresses those impacts. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than the manufacturing sector being regulated, caused by: (1) Reduced spending by end users on energy; (2) reduced spending on new energy supplies by the utility industry; (3) increased spending on new equipment to which the new standards apply; and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects of such shifts in economic activity on the demand for labor is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (BLS).[48] The BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from the BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[49] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing customer utility bills. Because reduced customer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.*, the utility sector) to more labor-intensive sectors (*e.g.*, the retail and manufacturing sectors). Thus, based on the BLS data alone, DOE believes that net national employment will increase

[48] Data on industry employment, hours, labor compensation, value of production, and the implicit price deflator for output for these industries are available upon request by calling the Division of Industry Productivity Studies (202–691–5618) or by sending a request by email to*dipsweb@bls.gov*. Available at: *www.bls.gov/news.release/prin1.nr0.htm*. (Last accessed October 2013.)

[49] *See* Bureau of Economic Analysis, *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II)*, Washington, DC, U.S. Department of Commerce, 1992.

due to shifts in economic activity resulting from new and amended standards for metal halide lamp fixtures.

For the standard levels considered in today's final rule, DOE estimated indirect national employment impacts using an input/output model of the U.S. economy called Impact of Sector Energy Technologies (ImSET), version 3.1.1.[50] ImSET is a special-purpose version of the "U.S. Benchmark National Input-Output" (I–O) model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE received several general comments at the NOPR public meeting questioning the validity of its employment analysis results. (Acuity, Public Meeting Transcript, No. 48 at p. 306; EEI, Public Meeting Transcript, No. 48 at pp. 298–301; GE, Public Meeting Transcript, No. 48 at p. 306; NEEA, Public Meeting Transcript, No. 48 at pp. 304–305; NEMA, Public Meeting Transcript, No. 48 at p. 302) DOE notes that ImSET is not a general equilibrium projection model and understands the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may overestimate actual job impacts over the long run for this rule. Because ImSET predicts small job impacts resulting from this rule, regardless of these uncertainties, the actual job impacts are likely to be negligible in the overall economy. DOE may consider the use of other modeling approaches for examining long-term employment impacts. DOE also notes that the indirect employment impacts estimated with ImSET for the entire economy differ from the direct employment impacts in the lighting manufacturing sector estimated using the GRIM in the MIA, as described at the beginning of this section. The methodologies used and the sectors analyzed in the ImSET and GRIM models are different.

For more details on the employment impact analysis, see chapter 14 of the final rule TSD.

[50] Roop, J. M., M. J. Scott, and R. W. Schultz, *ImSET 3.1: Impact of Sector Energy Technologies* (PNNL–18412 Pacific Northwest National Laboratory) (2009). Available at *www.pnl.gov/main/publications/external/technical_reports/PNNL-18412.pdf.* (Last accessed October 2013.)

K. Utility Impact Analysis

The utility impact analysis estimates several important effects on the utility industry of the adoption of new or amended standards. For this analysis, DOE used the NEMS–BT model to generate forecasts of electricity consumption, electricity generation by plant type, and electric generating capacity by plant type, that would result from each considered TSL. DOE obtained the energy savings inputs associated with efficiency improvements to considered equipment from the NIA. DOE conducts the utility impact analysis as a scenario that departs from the latest *AEO* Reference Case. For the August 2013 NOPR analysis, the estimated impacts of standards were the differences between values forecasted by NEMS–BT and the values in the *AEO2013* Reference Case. 78 FR 51464, 51512 (Aug. 20, 2013). DOE received no comments related to its utility impact analysis and retained its approach for this final rule. Chapter 15 of the final rule TSD describes the utility impact analysis.

L. Emissions Analysis

In the emissions analysis, DOE estimated the reduction in power sector emissions of CO_2, NO_X, SO_2, and Hg from potential energy conservation standards for metal halide lamp fixtures. In addition to estimating impacts of standards on power sector emissions, DOE estimated emissions impacts in production activities that provide the energy inputs to power plants. These are referred to as "upstream" emissions. In accordance with the FFC Statement of Policy (76 FR 51281 [August 18, 2011]), as amended at 77 FR 49701 (Aug. 17, 2012), this FFC analysis includes impacts on emissions of methane (CH_4) and nitrous oxide (N_2O), both of which are recognized as greenhouse gases.

DOE primarily conducted the emissions analysis using emissions factors for CO_2 and most of the other gases derived from data in *AEO2013*. Combustion emissions of CH_4 and N_2O were estimated using emissions intensity factors published by the Environmental Protection Agency (EPA), GHG Emissions Factors Hub.[51] Site emissions of CO_2 and NO_X were estimated using emissions intensity factors from an EPA publication.[52] DOE developed separate emissions factors for power sector emissions and upstream emissions. The method that DOE used to derive emissions factors is described in chapter 16 of the final rule TSD.

For CH_4 and N_2O, DOE calculated emissions reduction in tons and also in terms of units of carbon dioxide equivalent (CO_2eq). Gases are converted to CO_2eq by multiplying the physical units by the gas' global warming potential (GWP) over a 100-year time horizon. Based on the Fourth Assessment Report of the Intergovernmental Panel on Climate Change,[53] DOE used GWP values of 25 for CH_4 and 298 for N_2O.

EIA prepares the *Annual Energy Outlook* using NEMS. Each annual version of NEMS incorporates the projected impacts of existing air quality regulations on emissions. *AEO2013* generally represents current legislation and environmental regulations, including recent government actions, for which implementing regulations were available as of December 31, 2012.

SO_2 emissions from affected electricity-generating units (EGUs) are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous states and the District of Columbia (DC). SO_2 emissions from 28 eastern states and DC were also limited under the Clean Air Interstate Rule (CAIR; 70 FR 25162 [May 12, 2005]), which created an allowance-based trading program. CAIR was remanded to the EPA by the U.S. Court of Appeals for the District of Columbia Circuit, but it remained in effect. See *North Carolina* v. *EPA*, 550 F.3d 1176 (D.C. Cir. 2008); *North Carolina* v. *EPA*, 531 F.3d 896 (D.C. Cir. 2008). On July 6, 2011 EPA issued a replacement for CAIR, the Cross-State Air Pollution Rule (CSAPR). 76 FR 48208 (Aug. 8, 2011). On August 21, 2012, the D.C. Circuit issued a decision to vacate CSAPR. See *EME Homer City Generation, LP* v. *EPA*, 696 F.3d 7, 38 (D.C. Cir. 2012). The court ordered EPA to continue administering CAIR. The *AEO2013* emissions factors used for today's NOPR assume that CAIR remains a binding regulation through 2040.

[51] See *www.epa.gov/climoteleodership/guidance/ghg-emissions.html.*

[52] U.S. Environmental Protection Agency, *Compilotion of Air Pollutant Emission Factors, AP–42, Fifth Edition, Volume I: Stationary Point and Area Sources.* 1998. *www.epa.gov/ttn/chief/op42/index.html.*

[53] Forster, P., V. Ramaswamy, P. Artaxo, T. Berntsen, R. Betts, D.W. Fahey, J. Haywood, J. Lean, D.C. Lowe, G. Myhre, J. Nganga, R. Prinn, G. Raga, M. Schulz and R. Van Dorland. 2007: Changes in Atmospheric Constituents and in Radiative Forcing. In *Climate Chonge 2007: The Physicol Science Bosis.* Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change. S. Solomon, D. Qin, M. Manning, Z. Chen, M. Marquis, K.B. Averyt, M. Tignor and H.L. Miller, Editors. 2007. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. p. 212.

The attainment of emissions caps is typically flexible among EGUs and is enforced through the use of emissions allowances and tradable permits. Under existing EPA regulations, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the imposition of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by any regulated EGU. In past rulemakings, DOE recognized that there was uncertainty about the effects of efficiency standards on SO_2 emissions covered by the existing cap-and-trade system, but it concluded that negligible reductions in power sector SO_2 emissions would occur as a result of standards.

Beginning in 2015, however, SO_2 emissions will fall as a result of the Mercury and Air Toxics Standards (MATS) for power plants. 77 FR 9304 (Feb. 16, 2012). In the final MATS rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (HAP), and also established a standard for SO_2 (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO_2 emissions will be reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. *AEO2013* assumes that, in order to continue operating, coal plants must have either flue gas desulfurization or dry sorbent injection systems installed by 2015. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Under the MATS, NEMS shows a reduction in SO_2 emissions when electricity demand decreases (*e.g.*, as a result of energy efficiency standards). Emissions will be far below the cap that would be established by CAIR, so it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by any regulated EGU. Therefore, DOE believes that efficiency standards will reduce SO_2 emissions in 2015 and beyond.

CAIR established a cap on NO_X emissions in 28 eastern states and the District of Columbia. Energy conservation standards are expected to have little effect on NO_X emissions in those states covered by CAIR because excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions. However, standards would be expected to reduce NO_X emissions in the states not affected by the caps, so DOE estimated NO_X emissions reductions from the standards considered in today's final rule for these states.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would likely reduce Hg emissions. DOE estimated mercury emissions reduction using NEMS–BT based on *AEO2013*, which incorporates the MATS.

DOE received comments regarding the emissions analysis during the NOPR public meeting. EEI noted that the EPA recently proposed greenhouse gas emissions standards for new EGUs [54] and would issue standards for existing EGUs in 2014. EEI commented that these standards would have a significant effect on DOE's emission analysis and that they should be considered in the final rule. (EEI, Public Meeting Transcript, No. 48 at pp. 307–309) In a joint comment, the U.S. Chamber of Commerce and cosignatories [55] (hereafter the "U.S. Chamber *et al.*") agreed. (U.S. Chamber *et al.*, No. 58 at p. 7) As discussed previously in this section, the *AEO2013* emissions factors available for this final rule analysis reflect regulations implemented as of December 31, 2012, and DOE cannot consider proposed emission standards in setting potential equipment efficiency standards.[56] GE encouraged DOE to consider the additional emissions produced in manufacturing the larger fixtures needed to meet potential efficiency standards, and GE indicated that NEMA intended to evaluate the "carbon footprint" of its manufacturing processes. (GE, Public Meeting Transcript, No. 48 at pp. 311–312) DOE received no related emissions estimates in written comments; further, as discussed previously in section V.C of this final rule, DOE's engineering analysis indicated that higher efficiency fixtures would not be significantly larger than baseline fixtures. DOE believes that any incremental emissions increases from the manufacture of higher efficiency fixtures would be negligible in comparison to its overall emissions estimates, and DOE retained its *AEO*-based approach for this final rule emissions analysis.

[54] Standards of Performance for Greenhouse Gas Emissions from New Stationary Sources: Electric Utility Generating Units—Proposed Rule (September 20, 2013); pre-publication version at *www2.epa.gov/sites/production/files/2013-09/documents/20130920proposal.pdf* (Last accessed November 22, 2013).

[55] Cosignatories include the American Forest & Paper Association, American Fuel & Petrochemical Manufacturers, American Petroleum Institute, Council of Industrial Boiler Owners, National Association of Manufacturers, National Mining Association, and the Portland Cement Association.

[56] APPA commented that EPA new source performance standards are effective upon issuance of the proposed rule. (APPA, Public Meeting Transcript, No. 48 at p. 310) DOE disagrees, citing section III.B of the proposed rule that states the emission limit would apply to affected sources on the effective date of the final action.

M. Monetizing Carbon Dioxide and Other Emissions Impacts

As part of the development of this final rule, DOE considered the estimated monetary benefits likely to result from the reduced emissions of CO_2 and NO_X that are expected to result from each of the TSLs considered. In order to make this calculation, similar to the calculation of the NPV of customer benefit, DOE considered the reduced emissions expected to result over the lifetime of equipment shipped in the projection period for each TSL. This section summarizes the basis for the monetary values used for each of these emissions and presents the values considered in this rulemaking.

For today's final rule, DOE is relying on a set of values for the SCC that was developed by an interagency process. A summary of the basis for these values is provided in the following section, and a more detailed description of the methodologies used is provided as an appendix to chapter 17 of the final rule TSD.

1. Social Cost of Carbon

The SCC is an estimate of the monetized damages associated with an incremental increase in carbon emissions in a given year. It is intended to include (but is not limited to) changes in net agricultural productivity, human health, property damages from increased flood risk, and the value of ecosystem services. Estimates of the SCC are provided in dollars per metric ton of CO_2. A domestic SCC value is meant to reflect the value of damages in the United States resulting from a unit change in CO_2 emissions, while a global SCC value is meant to reflect the value of damages worldwide.

Under section 1(b) of E.O. 12866, agencies must, to the extent permitted by law, "assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." The purpose of the SCC estimates presented here is to allow agencies to incorporate the monetized social benefits of reducing CO_2 emissions into cost-benefit analyses of regulatory actions that have small, or "marginal," impacts on cumulative global emissions.

The estimates are presented with an acknowledgement of the many uncertainties involved and with a clear understanding that they should be updated over time to reflect increasing knowledge of the science and economics of climate impacts.

As part of the interagency process that developed these SCC estimates, technical experts from numerous agencies met on a regular basis to consider public comments, explore the technical literature in relevant fields, and discuss key model inputs and assumptions. The main objective of this process was to develop a range of SCC values using a defensible set of input assumptions grounded in the existing scientific and economic literatures. In this way, key uncertainties and model differences transparently and consistently inform the range of SCC estimates used in the rulemaking process.

a. Monetizing Carbon Dioxide Emissions

When attempting to assess the incremental economic impacts of CO_2 emissions, the analyst faces a number of serious challenges. A recent report from the National Research Council [57] points out that any assessment will suffer from uncertainty, speculation, and lack of information about (1) future emissions of GHGs, (2) the effects of past and future emissions on the climate system, (3) the impact of changes in climate on the physical and biological environment, and (4) the translation of these environmental impacts into economic damages. As a result, any effort to quantify and monetize the harms associated with climate change will raise serious questions of science, economics, and ethics and should be viewed as provisional.

Despite the serious limits of both quantification and monetization, SCC estimates can be useful in estimating the social benefits of reducing CO_2 emissions. Most Federal regulatory actions can be expected to have marginal impacts on global emissions. For such policies, the agency can estimate the benefits from reduced emissions in any future year by multiplying the change in emissions in that year by the SCC value appropriate for that year. The net present value of the benefits can then be calculated by multiplying each of these future benefits by an appropriate discount factor and summing across all affected years. This approach assumes that the marginal damages from increased emissions are constant for small departures from the baseline emissions path, an approximation that is reasonable for policies that have effects on emissions that are small relative to cumulative global CO_2 emissions. For policies that have a large (non-marginal) impact on global cumulative emissions, there is a separate question of whether the SCC is an appropriate tool for calculating the benefits of reduced emissions. This concern is not applicable to this notice, however.

It is important to emphasize that the interagency process is committed to updating these estimates as the science and economic understanding of climate change and its impacts on society improves over time. In the meantime, the interagency group will continue to explore the issues raised by this analysis and consider public comments as part of the ongoing interagency process.

b. Social Cost of Carbon Values Used in Past Regulatory Analyses

Economic analyses for Federal regulations used a wide range of values to estimate the benefits associated with reducing CO_2 emissions. The model year 2011 Corporate Average Fuel Economy final rule used both a "domestic" SCC value of $2 per metric ton of CO_2 and a "global" SCC value of $33 per metric ton of CO_2 for 2007 emission reductions (in 2007$), increasing both values at 2.4 percent per year. It also included a sensitivity analysis at $80 per metric ton of CO_2.[58] The proposed rule for Model Years 2011–2015 assumed a domestic SCC value of $7 per metric ton of CO_2 (in 2006$) for 2011 emission reductions (with a range of $0–$14 for sensitivity analysis), also increasing at 2.4 percent per year.[59] A regulation for packaged terminal air conditioners and packaged terminal heat pumps finalized by DOE in 2008 used a domestic SCC range of $0 to $20 per metric ton CO_2 for 2007 emission reductions (in 2007$). 73 FR 58772, 58814 (Oct. 7, 2008) In addition, EPA's 2008 Advance Notice of Proposed Rulemaking on Regulating Greenhouse Gas Emissions Under the Clean Air Act identified what it described as "very preliminary" SCC estimates subject to revision. 73 FR 44354 (July 30, 2008). EPA's global mean values were $68 and $40 per metric ton CO_2 for discount rates of approximately 2 percent and 3 percent, respectively (in 2006$ for 2007 emissions).

In 2009, an interagency process was initiated to offer a preliminary assessment of how best to quantify the benefits from reducing CO_2 emissions. To ensure consistency in how benefits are evaluated across agencies, the Administration sought to develop a transparent and defensible method, specifically designed for the rulemaking process, to quantify avoided climate change damages from reduced CO_2 emissions. The interagency group did not undertake any original analysis. Instead, it combined SCC estimates from the existing literature to use as interim values until a more comprehensive analysis could be conducted. The outcome of the preliminary assessment by the interagency group was a set of five interim values: Global SCC estimates for 2007 (in 2006$) of $55, $33, $19, $10, and $5 per ton of CO_2. These interim values represent the first sustained interagency effort within the U.S. government to develop an SCC for use in regulatory analysis. The results of this preliminary effort were presented in several proposed and final rules.

c. Current Approach and Key Assumptions

Since the release of the interim values, the interagency group reconvened on a regular basis to generate improved SCC estimates. The group considered public comments and further explored the technical literature in relevant fields. The interagency group relied on three integrated assessment models commonly used to estimate the SCC: The FUND, DICE, and PAGE models. These models are frequently cited in the peer-reviewed literature and were used in the last assessment of the Intergovernmental Panel on Climate Change. Each model was given equal weight in the SCC values that were developed.

Each model takes a slightly different approach to model how changes in emissions result in changes in economic damages. A key objective of the interagency process was to enable a consistent exploration of the three models while respecting the different approaches to quantifying damages taken by the key modelers in the field. An extensive review of the literature was conducted to select three sets of input parameters for these models: Climate sensitivity, socioeconomic and

[57] National Research Council. *Hidden Costs of Energy: Unpriced Consequences of Energy Production and Use.* National Academies Press: Washington, DC (2009).

[58] See *Average Fuel Economy Standards Passenger Cars and Light Trucks Model Year 2011*, 74 FR 14196 (March 30, 2009) (Final Rule); Final Environmental Impact Statement Corporate Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015 at 3–90 (Oct. 2008) (Available at: *www.nhtsa.gov/fuel-economy*).

[59] See *Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015*, 73 FR 24352 (May 2, 2008) (Proposed Rule); Draft Environmental Impact Statement Corporate Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015 at 3–58 (June 2008) (Available at: *www.nhtsa.gov/fuel-economy*).

emissions trajectories, and discount rates. A probability distribution for climate sensitivity was specified as an input into all three models. In addition, the interagency group used a range of scenarios for the socioeconomic parameters and a range of values for the discount rate. All other model features were left unchanged, relying on the model developers' best estimates and judgments.

The interagency group selected four sets of SCC values for use in regulatory analyses. Three values were based on the average SCC from three integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth value, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, were included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The values estimated for 2010 grow in real terms over time. Additionally, the interagency group determined that a range of values from 7 percent to 23 percent should be used to adjust the global SCC to calculate domestic effects, although preference is given to consideration of the global benefits of reducing CO_2 emissions. Table V.10 presents the values in the 2010 interagency group report,[60] which is reproduced in appendix 17A of the final rule TSD.

TABLE V.10—ANNUAL SCC VALUES FROM 2010 INTERAGENCY REPORT, 2010–2050

[In 2007 dollars per metric ton CO_2]

	Discount rate			
	5% Avg.	3% Avg.	2.5% Avg.	3% 95th
2010	4.7	21.4	35.1	64.9
2015	5.7	23.8	38.4	72.8
2020	6.8	26.3	41.7	80.7
2025	8.2	29.6	45.9	90.4
2030	9.7	32.8	50.0	100.0
2035	11.2	36.0	54.2	109.7
2040	12.7	39.2	58.4	119.3
2045	14.2	42.1	61.7	127.8
2050	15.7	44.9	65.0	136.2

The SCC values used for today's notice were generated using the most recent versions of the three integrated assessment models that have been published in the peer-reviewed literature.[61] Table V.11 shows the updated sets of SCC estimates in five-year increments from 2010 to 2050. The full set of annual SCC estimates between 2010 and 2050 is reported in appendix 17B of the final rule TSD. The central value that emerges is the average SCC across models at the 3 percent discount rate. However, for purposes of capturing the uncertainties involved in regulatory impact analysis, the interagency group emphasized the importance of including all four sets of SCC values.

TABLE V.11—ANNUAL SCC VALUES FROM 2013 INTERAGENCY UPDATE, 2010–2050

[In 2007 dollars per metric ton CO_2]

Year	Discount rate %			
	5	3	2.5	3
	Average	Average	Average	95th percentile
2010	11	32	51	89
2015	11	37	57	109
2020	12	43	64	128
2025	14	47	69	143
2030	16	52	75	159
2035	19	56	80	175
2040	21	61	86	191
2045	24	66	92	206
2050	26	71	97	220

It is important to recognize that a number of key uncertainties remain, and that current SCC estimates should be treated as provisional and revisable since they will evolve with improved scientific and economic understanding. The interagency group also recognizes that the existing models are imperfect and incomplete. The National Research Council report mentioned above points out that there is tension between the goal of producing quantified estimates of the economic damages from an incremental ton of CO_2 emissions and the limits of existing efforts to model these effects. There are a number of concerns and problems should be addressed by the research community, including research programs housed in many of the Federal agencies participating in the interagency process

[60] *Sociol Cost of Corbon for Regulotory Impoct Anolysis Under Executive Order 12866.* Interagency Working Group on Social Cost of Carbon, United States Government, 2010.

[61] Technical Support Document: Technical Update of the *Sociol Cost of Corbon for Regulotory Impoct Anolysis Under Executive Order 12866.* Interagency Working Group on Social Cost of Carbon, United States Government, May 2013 (Revised November 2013). *www.whitehouse.gov/sites/defoult/files/omb/ossets/inforeg/technicol-updote-sociol-cost-of-corbon-for-regulotor-impoct-onolysis.pdf.*

to estimate the SCC. The interagency group intends to periodically review and reconsider those estimates to reflect increasing knowledge of the science and economics of climate impacts, as well as improvements in modeling.

In summary, in considering the potential global benefits resulting from reduced CO_2 emissions, DOE used the values from the 2013 interagency report, adjusted to 2012$ using the Gross Domestic Product price deflator. For each of the four cases specified, the values used for emissions in 2015 were $11.8, $39.7, $61.2, and $117 per metric ton avoided (values expressed in 2012$).[62] DOE derived values after 2050 using the growth rate for the 2040–2050 period in the interagency update.

DOE multiplied the CO_2 emissions reduction estimated for each year by the SCC value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SCC values in each case.

In responding to the MHLF NOPR, many commenters questioned the scientific and economic basis of the SCC values. These commenters made extensive comments about: The alleged lack of economic theory underlying the models; the sufficiency of the models for policy-making; potential flaws in the models' inputs and assumptions (including the discount rates and climate sensitivity chosen); whether there was adequate peer review of the three models; whether there was adequate peer review of the TSD supporting the 2013 SCC values; whether the SCC estimates comply with OMB's "Final Information Quality Bulletin for Peer Review" [63] and DOE's own guidelines for ensuring and maximizing the quality, objectivity, utility and integrity of information disseminated by DOE; whether DOE's use of the updated SCC values has precedential effect for other agency rulemakings; and why DOE is considering global benefits of carbon dioxide emission reductions rather than solely domestic benefits. (Mercatus Center, No. 57 at pp. 1–6; NEMA, No. 56 at pp. 25–31, U.S. Chamber *et al.*, No. 58 at pp. 4–8)

On November 26, 2013, the Office of Management and Budget (OMB) announced minor technical corrections to the 2013 SCC values and a new opportunity for public comment on the revised TSD underlying the SCC estimates. Comments regarding the underlying science and potential precedential effect of the SCC estimates resulting from the interagency process should be directed to that process. *See* 78 FR 70586. Additionally, several current rulemakings also use the 2013 SCC values and the public is welcome to comment on the values as applied in those rulemakings just as the public was welcome to comment on the use and application of the 2010 SCC values in the many rules that were published using those values in the past three years.

The U.S. Chamber *et al.* also stated that DOE calculates the present value of the costs of the NOPR to customers and manufacturers over a 30-year period. The SCC values, on the other hand, reflect the present value of future climate related impacts well beyond 2100. According to the U.S. Chamber *et al.*, DOE's comparison of 30 years of cost to hundreds of years of presumed future benefits is inconsistent and improper. (U.S. Chamber *et al.*, No. 58 at pp. 5–6)

For the analysis of national impacts of the adopted standards, DOE considered the lifetime impacts of fixtures shipped in a 30-year period. With respect to energy and energy cost savings, impacts continue past 30 years until all of the fixtures shipped in the 30-year period are retired. With respect to the valuation of CO_2 emissions reductions, DOE considers the avoided emissions over the same period as the energy savings. CO_2 emissions have on average a very long residence time in the atmosphere. Thus, emissions in the period considered by DOE would contribute to global climate change over a very long time period, with associated social costs. The SCC for any given year represents the discounted present value, in that year and expressed in constant dollars, of a lengthy stream of future costs estimated to result from emission of a ton of CO_2. It is worth pointing out that because of discounting, the present value of costs in the distant future is very small. DOE's accounting of energy cost savings and the value of avoided CO_2 emissions reductions is consistent: Both consider the complete impacts associated with products shipped in the 30-year period.

2. Valuation of Other Emissions Reductions

DOE investigated the potential monetary benefit of reduced NO_X emissions from the TSLs it considered. As noted in section V.L, DOE has taken into account how new energy conservation standards would reduce NO_X emissions in those 28 states that are not affected by emissions caps. DOE estimated the monetized value of NO_X emissions reductions resulting from each of the TSLs considered for today's final rule based on estimates found in the relevant scientific literature. Estimates of monetary value for reducing NO_X from stationary sources range from $468 to $4,809 per ton (in 2012$).[64] DOE calculated the monetary benefits using a medium value for NO_X emissions of $2,639 per short ton (in 2012$) and real discount rates of 3 percent and 7 percent.

DOE is evaluating appropriate monetization of avoided SO_2 and Hg emissions in energy conservation standards rulemakings. It has not included monetization in the current analysis.

VI. Other Issues for Discussion

A. Proposed Standard Levels in August 2013 NOPR

In the NOPR, DOE proposed new and revised energy conservation standards for all equipment classes. Specifically, DOE proposed TSL 3, which comprised EL2 for all equipment classes except the 100 W–150 W indoor and outdoor equipment classes, for which DOE proposed EL4. DOE received comment from several interested parties regarding these proposals.

ULT noted the proposal that 150 W MHLFs exempted by EISA 2007 (fixtures designed for use in high temperature and wet environments) were subject to EL4, while 150 W MHLFs not exempted by EISA 2007 were only subject to EL2. ULT questioned why the NOPR proposed lower efficiencies for fixtures that operate in less severe conditions. (ULT, No. 50 at p. 2) As discussed previously in section V.A.2 of this notice, the EISA 2007 exemption for certain 150 W MHLFs led to a difference in the commercially available efficiencies in MH ballasts that are exempt or are not exempt from EISA 2007. As a result, DOE proposed that 150 W MHLFs previously exempt by EISA 2007 be included in the 101 W–150 W range, while 150 W MHLFs subject to EISA 2007 standards continue to be included in the 150 W–250 W range. For the 101 W–150 W MHLFs, DOE found that EL4, the max-tech level, was economically justified. However, for the 150 W–250

[62] The interagency report presents SCC values through 2050. DOE derived values after 2050 using the 3-percent per year escalation rate used by the interagency group.

[63] Available at: *http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf*

[64] U.S. Office of Management and Budget, Office of Information and Regulatory Affairs, *2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities,* Washington, DC.

W MHLFs, DOE found that the maximum EL achievable with positive NPV was the magnetic ballast max-tech level, EL2 at 88.0 percent. Therefore, in the NOPR, the economic results for the nation supported a higher standard for MHLFs included in the 101 W–150 W range.

ULT commented that NOPR TSL 3 requires a shift to electronic ballasts, which will not work very well in outdoor applications. Further, ULT noted that the NOPR TSLs all appeared to be modeled or mandated without regard to the application, and seemed not to make practical sense. (ULT, Public Meeting Transcript, No. 48 at p. 215). NEMA and ULT commented that NOPR TSL 3 would require a shift to electronic ballasts in 70 W, 150 W, and 250 W fixtures, ban probe-start ballasts, and eliminate many of the magnetic ballast performance features, as these are not feasible in the mandated electronic HF ballasts. (NEMA, No. 56 at p. 24; ULT, No. 50 at p. 16). ULT commented that there should be some way to validate the TSLs. ULT suggested that DOE should build these models, and then allow the manufacturers to test them. They explained that results are much different in a lab environment with more resources and time than in manufacturing facilities that make hundreds of ballasts every 15 minutes. In situations with many variable materials, modeled and laboratory efficiencies differ greatly from those feasibly possible in a manufacturing facility. (ULT, Public Meeting Transcript, No. 48 at pp. 216, 218) ULT stated that overall the NOPR TSLs are too stringent, and proposed different standards. (ULT, No. 50 at p. 16)

DOE acknowledges that standards proposed for 100 W–150 W MHLFs in the NOPR would require a shift to electronic ballasts. While DOE recognizes that magnetic ballasts are inherently more robust than electronic ballasts, the NOPR accounted for the cost of added protection to electronic ballasts in outdoor applications. DOE continues to use this methodology in this final rule. For details of the determination that electronic ballasts could be used in these same applications with certain cost adders, see section V.C.8.b. For details of the cost adders required by electronic ballasts being used in the same application as magnetic ballasts, see section V.C.12.

DOE has modeled ballasts in both the NOPR and final rule, utilizing teardown data and manufacturer input. Further research and refinement was performed for the modeled ballasts for this final rule in response to comments. See section V.C.8 for discussion of these models. DOE has not included high-frequency electronic ballasts in the scope of this rulemaking because there is no test method for them. See section III.A.4 for more details. As a result, none of the ELs analyzed in this final rule require high-frequency electronic ballasts. A more detailed discussion of the TSLs newly analyzed and chosen in this final rule is available later in this section.

ASAP urged DOE to adopt the maximum cost-effective ELs. (ASAP, Public Meeting Transcript, No. 48 at p. 17) DOE analyzed several combinations of ELs in the NOPR and in the final rule. These combinations of ELs, called TSLs, can represent many criteria, including maximum energy savings, technology descriptions (such as all max-tech magnetic ELs), or maximum energy savings with cost effective ELs. As discussed in section VII.C of this notice, DOE adopted the TSL that saved the most energy and was economically justified for customers, manufactures, and the nation based on a weighing of costs and benefits.

ULT commented that NOPR TSL 3 did not meet the requirement of a three-year PBP, but instead PBPs seemed to range from 4 to 14 years (ULT, No. 50 at p. 15). DOE does not have a specific minimum PBP requirement. Each equipment class is analyzed individually based on the market and economic analyses and the cost and benefits of all results are weighted. See section VII.B.1.a for discussions of the PBPs associated with the levels analyzed in this final rule.

NEMA commented that it is very difficult to determine the final net benefit of TSL 3 from NOPR Tables VI.47 and VI.48, and DOE has not aided the reader in understanding its conclusion. (NEMA, No. 56 at p. 25). NEMA commented that DOE appropriately considered a range of values for carbon emissions reductions, but noted that these values are only informative and should not be used for regulatory decision-making. (NEMA, No. 56 at p. 26).

In this final rule, DOE analyzed the benefits and burdens of a number of TSLs for the metal halide lamp fixtures that are the subject of today's final rule. In accordance with (42 U.S.C. 6295(o)(2)(B)(i)), DOE must weigh the cost and benefits of seven factors, including other factors the Secretary considers relevant. DOE continues to present and consider a range of carbon emission reduction values in its weighing of the costs and benefits of any adopted standard. Regarding presentation of a final net benefit value, DOE directs NEMA to Table I.4.

The Joint Comment suggested that DOE evaluate an additional TSL, identical to NOPR TSL 5 except that efficiency levels for 250–500 W ballasts would be based on EL3, which represents low-frequency electronic ballasts. (Joint Comment, No. 62 at p. 5). As discussed in section III.A.4, DOE is no longer considering standards that require use of high-frequency electronic ballasts because they are not in the scope of this rulemaking. Therefore, the max-tech levels for 50 W–1000 W fixtures are all represented by low-frequency ballasts, removing the need for the additional TSL suggested by the Joint Comment.

B. Reported Value

The sampling and reporting for the testing of MHLFs and, by extension, MH ballasts are provided for in 10 CFR 429.54. The reported value for the tested ballast efficiency of a model must be less than or equal to the lower of the mean of the samples tested or the lower 99 percent confidence limit (LCL) of the true mean divided by 0.99.

CA IOUs supported DOE's proposal to apply a confidence interval, which is consistent with the approach used for other products and accounts for variation in product testing and manufacturing. (CA IOUs, No. 54 at p. 3). Some stakeholders commented that because of the variation present in MHLFs, standard levels should be rounded to the nearest whole number rather than tenth of a percent (i.e., 88 percent rather than 88.0 percent). ULT and NEMA noted the variations in wire cross sections (up to 3 percent) and core lamination thickness (up to 10 percent) create efficiency losses in the ballasts. The combination of efficiency losses in these two areas and variability in manufacturing combined with the 99 percent confidence factor, makes the precise proposed levels unachievable in full-scale manufacturing facilities. (ULT, Public Meeting Transcript, No. 48 at pp. 34, 90; NEMA, Public Meeting Transcript, No. 48 at p. 34; NEMA, No. 44 at pp. 10, 13; ULT, No. 50 at pp. 3–4, 25–29). Further, NEMA noted that its white paper NEMA LSD–63–2012 on variability estimated the tolerance for a sample of four magnetic ballasts to be 4.7 percent when a confidence factor of 99 percent is required. (NEMA, No. 56 at p. 8) Due to the variability of raw material properties resulting in varied efficiencies, NEMA, Musco Lighting, and ULT suggested a less precise designation of the efficiency threshold. NEMA and ULT suggested carrying out all calculations to the tenth of a decimal

place, with the result then rounded to the nearest integer using the round half up rule. Musco Lighting agreed, suggesting reporting ballast efficiency as a whole integer. (NEMA, No. 56 at p. 8; Musco Lighting, No. 55 at p. 4; ULT, No. 50 at pp. 3, 4, 25; ULT, Public Meeting Transcript, No. 48 at p. 38). NEMA also commented that it would be better to have less precise standards initially, so that tolerances would not have to be created when verification and enforcement actions are made by DOE. (NEMA, Public Meeting Transcript, No. 48 at p. 82)

ULT and NEMA noted that certain ballasts they manufacture, which are currently compliant with EISA 2007, would not meet the same requirements under the proposed rounding system (to the nearest tenth of a percent). (ULT, No. 50 at pp. 3–4; ULT, No. 50 at p. 25; ULT, Public Meeting Transcript, No. 48 at p. 38; NEMA, No. 44 at p. 14). Earthjustice asserted that current equipment that would not meet standards with the new rounding regulations should not be grandfathered in under the new statute. (Earthjustice, Public Meeting Transcript, No. 48 at p. 86).

As discussed in section IV.A of this notice, DOE has determined that the calculation of ballast efficiency is possible to the a tenth of a percent. In addition to information available in industry standards, data submitted by manufacturers has substantiated this conclusion in that it is represented to the tenth of a percent for some ballasts and fixtures in DOE's CCE database. DOE will establish energy conservation standards using the same number of significant figures (three) as the test procedure provides. Test data collected in support of the energy conservation standard was conducted in accordance with the test procedure in 10 CFR 431.324. The certification requirements of 10 CFR 429.54 includes sampling plans that are designed to create conservative ratings, which ensures that customers get—at a minimum—the efficiency indicated by the certified rating. Therefore, DOE's analysis considers levels of efficiency achievable given current manufacturing and material variability. Thus, standards are established and compliance with the standards determined by rounding the reported value to three significant figures. For 150 W–200 W fixtures that will be subject to a standard of 88.0 percent, DOE has accounted for redesign and retesting costs in the MIA by estimating that all MH ballasts at the baseline efficiency level for this wattage range will need to be redesigned if higher efficiency standards are adopted. DOE includes the redesign, retesting, and recertification costs as part of conversion costs of the MIA (see section V.I.4 of this notice for a complete description of the conversion costs used in the MIA).

C. Three-Year Compliance Date

In the NOPR, DOE noted that EPCA, as amended by EISA 2007, contains guidelines for the compliance date of the standards adopted by this rulemaking. EPCA required DOE to determine whether to amend the standards in effect for metal halide lamp fixtures and whether any amended standards should apply to additional metal halide lamp fixtures. The Secretary was directed to publish a final rule no later than January 1, 2012 to determine whether the energy conservation standards established by EISA 2007 for metal halide lamp fixtures should be amended, with any amendment applicable to products manufactured after January 1, 2015. (42 U.S.C. 6295(hh)(2)(B)) In the NOPR public meeting, DOE presented the planned publication date of the final rule to be in January 2014 and proposed a compliance date of January 1, 2015.

Several stakeholders commented on DOE's plan to publish a final rule in January 2014. APPA noted that the compliance date proposed in the NOPR is unreasonable from a process standpoint. DOE would have three months between the end of the NOPR comment period to the publication of the final rule, which is a much faster turnaround than previous rules. (APPA, No. 51 at p. 3) EEI also clarified that based on a January 2014 publication, DOE is only giving itself three months between receiving comments and issuing a final rule. (EEI, Public Meeting Transcript, No. 48 at p. 44) Musco Lighting commented that issuing the final rule in January 2014 would not provide sufficient time to appropriately review comments and modify analyses. (Musco Lighting, No. 55 at p. 4) APPA commented that it is important to consider how long the review processes of the Office of Management and Budget have taken in previous rulemakings. (APPA, No. 51 at p. 3)

DOE has had sufficient time for this particular rulemaking to consider and develop responses to the comments received on the NOPR and complete the final rule analyses.

DOE received several comments regarding the proposed amount of time between the publication of the final rule and the date manufacturers are required to comply with any amended standards. APPA and EEI commented that, according to workshop handouts and based on language in EISA 2007, DOE plans to issue a final rule in January 2014 with an effective date of January 1, 2015. (APPA, No. 51 at p. 3; EEI, No. 53 at p. 2, 3) Considering this, APPA and Musco Lighting found that manufacturers could possibly be given less than 11 months to comply with the new final rule. (APPA, No. 51 at p. 3; Musco Lighting, No. 55 at p. 4) NEMA, ASAP, and NRCA noted that, while the 2015 date was stipulated by 42 U.S.C. 6295(hh)(2), this was assuming the final rule would be completed by January 1, 2012 and the intent of EISA 2007 was to provide manufacturers with a three-year period before compliance to allow for investments and manufacturing conversion, as well as allowing customers sufficient time to make any necessary changes. NEMA, APPA, and NRCA stated that adopting anything shorter than three years is not reasonable. (NEMA, No. 56 at p. 3, 20; NEMA, Public Meeting Transcript, No. 48 at p. 21; NEMA, No. 44 at p. 2; APPA, No. 51 at p. 3; NRCA, No. 61 at p. 1) ASAP agreed that it is not reasonable to provide less than one year for manufacturers to adjust for compliance, especially considering DOE did not comply with the provisions included in EISA 2007 by not issuing a final rule by January 1, 2012. (APPA, No. 51 at p. 3) ULT commented that standard practice is three years after final rule and APPA urged DOE to provide manufacturers and customers with a three-year period between publication of the final rule and the effective date. (ULT, No. 50 at p. 14; APPA, No. 51 at p. 3)

Stakeholders provided several reasons to support the need for a three-year interval between the publication of the final rule and the date of compliance. NEMA and UL noted this standard is much more complex and has a broader scope than the ones specified in EISA 2007, and that this standard has implications on both ballast and fixture manufacturers. (NEMA, Public Meeting Transcript, No. 48 at p. 19; NEMA, No. 44 at p. 2; ULT, No. 50 at p. 14) NEMA noted that, with this rulemaking's expanded scope, manufacturers would have to evaluate products not previously covered by EISA 2007, determine what products can be redesigned and which need to be eliminated, test new and modified ballasts for performance and safety, educate internal staff and customers, reevaluate inventory management, reevaluate manufacturing strategies, modify marketing materials, and work with suppliers and sellers. All of those logistics are required to take place and

make January 2015 an unreasonable compliance date, according to NEMA. (NEMA, Public Meeting Transcript, No. 48 at pp. 21, 27; NEMA, No. 44 at pp. 2–3, 5) NEMA also commented that while the standards specified in EISA 2007 primarily impacted industrial and outdoor channels, this rulemaking would impact new channels, such as retail consumer products and commercial offices with the lower wattage products. (NEMA, Public Meeting Transcript, No. 48 at p. 19; NEMA, No. 44 at p. 2)

NEMA and Musco Lighting noted that with any increased efficiency numbers there are numerous product redesigns required, so it is imperative that DOE provide industry with the full three years to bring their products to compliance. (NEMA, No. 56 at pp. 20–21; Musco Lighting, No. 55 at p. 4) ULT noted the commercial market is far from the NOPR proposed levels, so there will need to be time for R&D and to prototype potential solutions. ULT commented that typical design time, taking into consideration Design Validation Testing, Life Test, UL, and other aspects of the process, is typically eight to twelve months. Even if they were moving three projects at once they would not be able to fully redesign the necessary products before January 2015, and they would run out of raw materials. (ULT, No. 50 at p. 14) NEMA and ULT also commented that DOE has to account for fixture manufacturers who would not be able to redesign their products until they had samples produced on a commercial scale from the ballast manufacturers. (NEMA, Public Meeting Transcript, No. 48 at p. 19; ULT, No. 50 at p. 14)

NEMA noted that the difficulties with completing all of these redesigns with such a short compliance period include having fewer employees working on MHLFs than there were in 2007 and having resources focused on R&D for other technologies. Taking resources from these areas to complete the necessary redesigns would also divert the speed of the market transition to more efficient technologies. (NEMA; No. 44 at p. 2) Southern Company also expressed concern that a compliance date of January 1, 2015, would force manufacturers to divert resources from the development and implementation of energy efficient technologies, such as LED, and this would increase the cost to customers and slow the conversion to LED. (Southern Company, No. 64 at p. 3)

The Joint Comment noted that if the compliance date of the rulemaking is three years after the final rule is published, the delayed compliance date would decrease the potential energy savings from the rulemaking. While the Joint Comment recognizes that compliance with standards with a one-year compliance period may not be feasible, the Joint Comment urged DOE to attempt to balance additional energy savings from an earlier effective date with the impacts on manufacturers. (Joint Comment, No. 62 at p. 10)

DOE recognizes that any compliance date subsequent to January 1, 2015, will lead to reduced energy savings compared to the NOPR. However, DOE believes that it would be difficult for both ballast and fixture manufacturers to redesign their product lines given the compliance date proposed in the NOPR. As such, this final rule has revised the compliance date to be three years after publication of this final rule in the **Federal Register**.

VII. Analytical Results

A. Trial Standard Levels

In the following sections, DOE presents the analytical results for the TSLs of the equipment classes that DOE analyzed directly. DOE scaled the ELs for these representative equipment classes to create ELs for other equipment classes that were not directly analyzed as set forth in chapter 5 of the TSD. For more details on the representative equipment classes, please see section V.C.2.

TABLE VII.1—TRIAL STANDARD LEVELS

Rep. Wattage	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
70 W Indoor	EL1	EL2	EL2	EL3	EL4.
70 W Outdoor	EL1	EL2	EL2	EL3	EL4.
150 W Indoor	EL1	EL2	EL2	EL3	EL4.
150 W Outdoor	EL1	EL2	EL2	EL3	EL4.
250 W Indoor	EL1	EL1	EL2	EL3	EL4.
250 W Outdoor	EL1	EL1	EL2	EL3	EL4.
400 W Indoor	EL1	EL2	EL2	EL3	EL4.
400 W Outdoor	EL1	EL2	EL2	EL3	EL4.
1000 W Indoor	EL2+DS	EL2+DS	EL2+DS	EL2+DS	EL2+DS.
1000 W Outdoor	EL2+DS	EL2+DS	EL2+DS	EL2+DS	EL2+DS.
1500 W Indoor	Baseline	Baseline	Baseline	EL1	EL2.
1500 W Outdoor	Baseline	Baseline	Baseline	EL1	EL2

* DS is a design standard that bans the use of probe-start ballasts in new metal halide lamp fixtures.

TSL 5 represents the max-tech efficiency levels available. TSL 5 would set energy conservation standards at EL4 for indoor and outdoor fixtures at 70 W, 150 W, 250 W, and 400 W. Energy conservation standards for indoor and outdoor fixtures at 1000 W, and 1500 W are set at EL2. TSL 5 also includes a design standard for indoor and outdoor 1000 W fixtures that prohibits the sale of probe-start ballasts in new fixtures. Standards included in TSL 5 require fixtures that contain max-tech electronic ballasts using high-grade electronic components, while indoor and outdoor fixtures at 1000 and 1500 W require max-tech magnetic ballasts using high-grade steel and copper windings. All ballasts required by TSL 5 are commercially available, except indoor and outdoor 1000 W and 1500 W ballasts, which are modeled.[65] TSL 5 sets the same standards for indoor and outdoor representative equipment classes at the same wattage.

TSL 4 represents the next highest efficiency levels in classes where efficiency levels were not justified at TSL 5. TSL 4 would set energy conservation standards at EL3 for indoor and outdoor fixtures at 70 W, 150 W, 250 W, and 400 W. Energy conservation standards for indoor and outdoor fixtures at 1000 W are set at EL2, and standards for indoor and outdoor fixtures at 1500 W are set at EL1. TSL 4 also includes a design standard for

[65] The 501 W–1000 W equipment class requires modeled 1000 W ballasts, but 875 W ballasts are commercially available.

indoor and outdoor 1000 W fixtures that prohibits the sale of probe-start ballasts in new fixtures. Standards included in TSL 4 require fixtures that include standard-grade electronic ballasts, while indoor and outdoor fixtures at 1000 W require max-tech magnetic ballasts using high grade steel and copper windings, and 1500 W ballasts are mid-grade magnetic ballasts requiring mid-grade steel and copper wiring. At TSL 4, all ballasts are commercially available, with the exception of the 1000 W ballasts, which are modeled.[65] TSL 4 sets the same standards for indoor and outdoor representative equipment classes at the same wattage.

TSL 3 represents the next highest efficiency levels in classes where efficiency levels were not justified at TSL 4, while also requiring the same EL for both indoor and outdoor fixtures at the same wattage. TSL 3 would set energy conservation standards at EL2 for all classes except 1500 W, which would remain at baseline levels. TSL 3 also includes a design standard for indoor and outdoor 1000 W fixtures that prohibits the sale of probe-start ballasts in new fixtures. Except for 1500 W fixtures, the standards included in TSL 3 require fixtures that include max-tech magnetic ballasts using high-grade steel and copper windings. Any ballast could be used with 1500 W fixtures because no efficiency level is proposed for them. At TSL 3 only the 1500 W ballasts are commercially available, while the other wattages were modeled.[65] TSL 3 sets the same standards for indoor and outdoor representative equipment classes at the same wattage.

TSL 2 represents the highest magnetic ELs that have positive NPVs, and also requires the same EL for both indoor and outdoor fixtures at the same wattage. TSL 2 would set energy conservation standards at EL2 for indoor and outdoor fixtures at 70 W, 150 W, 400 W, and 1000 W. TSL 2 would require EL1 for 250 W indoor and outdoor fixtures, while all 1500 W fixtures would have no energy conservation standards (baseline). TSL 2 also includes a design standard for indoor and outdoor 1000 W fixtures that prohibits the sale of probe-start ballasts in new fixtures. Standards included in TSL 2 require fixtures that include max-tech magnetic ballasts requiring high-grade steel and copper windings, although 250 W ballasts typically require mid-grade steel and copper windings, and any ballast could be used with the unregulated 1500 W fixtures. At TSL 2 the 70 W, 150 W, 400 W, and 1000 W indoor and outdoor ballasts are not commercially available, and have been modeled,[65] while 250 W and 1500 W indoor and outdoor ballasts are commercially available. TSL 2 sets the same standards for indoor and outdoor representative equipment classes at the same wattage.

TSL 1 represents EL1 at all equipment classes, except at 1000 W, in which EL2 and a design standard is required, and 1500 W, in which no standards are established. TSL 1 would set energy conservation standards at EL1 for indoor and outdoor fixtures at 70 W, 150 W, 250 W, and 400 W, while setting standards at EL2 for indoor and outdoor 1000 W fixtures, and no standards for 1500 W fixtures. TSL 1 also includes a design standard for indoor and outdoor 1000 W fixtures that prohibits the sale of probe-start ballasts in new fixtures. TSL 1 requires fixtures that include magnetic ballasts using mid-grade steel and copper windings, although 1000 W will require max-tech ballasts using high-grade steel and copper windings. At TSL 1 the only ballasts that are not commercially available are in the 400 W and 1000 W classes, which have been modeled.[65] TSL 1 sets the same standards for indoor and outdoor representative equipment classes at the same wattage.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Customers

a. Life-Cycle Cost and Payback Period

To evaluate the net economic impact of standards on customers, DOE conducted LCC and PBP analyses for each TSL. In general, a higher efficiency product would affect consumers in two ways: (1) Annual operating expense would decrease; and (2) purchase price would increase. Section V.F of this rulemaking discusses the inputs DOE used for calculating the LCC and PBP.

The key outputs of the LCC analysis are a mean LCC savings relative to the baseline case, as well as a probability distribution or likelihood of LCC reduction or increase, for each TSL and equipment class. These values are reported by equipment class in Table VII.2 through Table VII.15. The LCC analysis also estimates the fraction of customers for which the LCC will decrease (net benefit) or increase (net cost) relative to the baseline case. The last column in each table contains the median PBPs for the customer purchasing a design compliant with the TSL. DOE assumed that, on average, indoor and outdoor fixtures have 20- and 25-year lifetimes, respectively.

TABLE VII.2—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (INDOOR, MAGNETIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline ...	442.74	955.48	1398.23	.....	.....	.....	.....
1	1	445.68	925.58	1371.26	26.97	0	100	1.4
2, 3	2	454.07	917.16	1371.23	27.00	0	100	4.5
4	3	459.38	896.35	1355.72	42.50	18	82	3.7
5	4	472.78	888.19	1360.97	37.25	21	79	6.0

TABLE VII.3—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (INDOOR, ELECTRONIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
1, 2, 3, 4	Baseline/3	459.38	896.35	1355.72	.....	.....	.....	.....
5	4	472.78	888.19	1360.97	−5.25	90	10	31.5

TABLE VII.4—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR, MAGNETIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	793.69	2195.72	2989.41	.....	.....	.....	.....
1	1	796.50	2158.67	2955.17	34.24	2	98	1.4
2, 3	2	804.53	2149.99	2954.53	34.88	3	97	4.5
4	3	834.98	2159.40	2994.38	−4.98	49	51	12.0
5	4	847.83	2152.73	3000.55	−11.15	51	49	14.7

TABLE VII.5—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR, ELECTRONIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
1, 2, 3, 4	Baseline/3	834.98	2159.40	2994.38	.....	.....	.....	.....
5	4	847.83	2152.73	3000.55	−6.17	88	12	55.8

TABLE VII.6—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	483.03	1521.22	2004.25	.....	.....	.....	.....
1	1	491.93	1489.89	1981.82	22.43	0	100	4.3
2, 3	2	504.66	1474.96	1979.62	24.63	1	99	7.3
4	3	503.20	1411.38	1914.58	89.67	6	94	2.5
5	4	522.42	1405.72	1928.14	76.11	11	89	4.8

TABLE VII.7—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	808.79	2679.99	3488.78	.....	.....	.....	.....
1	1	817.32	2644.09	3461.41	27.37	3	97	4.5
2, 3	2	829.51	2628.57	3458.08	30.70	3	97	8.1
4	3	855.33	2581.21	3436.54	52.23	34	66	7.5

TABLE VII.7—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
5	4	873.73	2578.45	3452.18	36.60	38	62	10.3

TABLE VII.8—EQUIPMENT CLASS 3—250 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	541.02	2122.17	2663.19				
1, 2	1	564.55	2094.13	2658.68	4.51	40	60	14.2
3	2	581.65	2082.60	2664.26	−1.07	63	37	17.9
4	3	611.53	2111.32	2722.85	−59.67	82	18	113.2
5	4	604.31	2099.21	2703.52	−40.33	71	29	38.4

TABLE VII.9—EQUIPMENT CLASS 3—250 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	1009.36	3153.36	4162.72				
1, 2	1	1031.89	3124.09	4155.98	6.74	33	67	17.4
3	2	1048.27	3112.97	4161.24	1.48	55	45	22.8
4	3	1109.39	3172.98	4282.37	−119.65	76	24	326.7
5	4	1102.47	3158.11	4260.58	−97.86	71	29	135.1

TABLE VII.10—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	628.46	3120.84	3749.31				
1	1	669.22	3077.26	3746.48	2.83	53	47	16.2
2, 3	2	686.23	3055.12	3741.36	7.95	46	54	15.0
4	3	756.96	3100.09	3857.05	−107.74	92	8	369.2
5	4	798.21	3081.70	3879.91	−130.60	94	6	137.2

TABLE VII.11—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	1077.56	4040.60	5118.16				
1	1	1116.59	3995.41	5112.00	6.16	45	55	19.9
2, 3	2	1132.88	3972.13	5105.01	13.15	38	62	18.4
4	3	1229.74	4053.72	5283.46	−165.30	81	19	Never

TABLE VII.11—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
5	4	1269.24	4036.62	5305.85	−187.69	84	16	Never

TABLE VII.12—EQUIPMENT CLASS 5—1000 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	760.77	7861.06	8621.83				
	Base+DS*	0.00	0.00	0.00	0.00	0	0	0.0
	Base+DS**	810.04	8025.13	8835.17	−213.34	100	0	N/A
	1	816.70	7795.42	8612.12	9.71	45	55	15.2
	1 + DS*	801.73	6617.67	7419.40	1202.43	0	100	0.5
	1 + DS**	865.97	7959.48	8825.46	−203.63	100	0	Never
	2	837.75	7770.63	8608.38	13.45	45	55	15.2
1, 2, 3, 4, 5	2 + DS*	830.98	6569.31	7400.29	1221.54	0	100	0.8
	2 + DS**	887.02	7934.70	8821.72	−199.89	100	0	Never

*DS = Design Standard prohibits fixtures from containing a probe-start ballast. A percentage of customers in this equipment class will migrate to these fixtures, which are reduced-wattage 875 W systems.

**Design Standard 1000 W pulse-start fixtures. Customers who do not migrate to 875 W systems will choose these 1000 W systems.

TABLE VII.13—EQUIPMENT CLASS 5—1000 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
	Baseline	1184.62	9152.48	10,337.10				
	Base+DS*	0.00	0.00	0.00	0.00	0	0	0.0
	Base+DS**	1239.95	9435.92	10,675.88	−338.78	100	0	N/A
	1	1238.18	9081.54	10,319.72	17.37	30	70	17.0
	1 + DS*	1231.48	7497.64	8729.12	1607.97	0	100	0.5
	1 + DS**	1293.52	9364.98	10,658.50	−321.40	100	0	Never
	2	1258.34	9054.76	10,313.10	24.00	30	70	17.0
1, 2, 3, 4, 5	2 + DS*	1259.49	7445.67	8705.16	1631.94	2	98	0.8
	2 + DS**	1313.68	9338.20	10,651.88	−314.78	100	0	Never

*DS = Design Standard prohibits fixtures from containing a probe-start ballast. A percentage of customers in this equipment class will migrate to these fixtures, which are reduced-wattage 875 W systems.

**Design Standard 1000 W pulse-start fixtures. Customers who do not migrate to 875 W systems will choose these 1000 W systems.

TABLE VII.14—EQUIPMENT CLASS 6—1500 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
1, 2, 3	Baseline	908.54	914.31	1822.86	0.00			
4	1	980.76	909.25	1890.01	−67.15	100	0	209.4
5	2	1010.83	905.09	1915.92	−93.06	100	0	162.7

TABLE VII.15—EQUIPMENT CLASS 6—1500 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
1, 2, 3	Baseline	1276.71	1203.04	2479.75	0.00			
4	1	1345.86	1197.60	2543.46	−63.71	100	0	244.5
5	2	1374.66	1193.11	2567.78	−88.03	100	0	190.0

b. Customer Subgroup Analysis

Using the LCC spreadsheet model, DOE determined the effect of the trial standard levels on the following customer subgroups: utilities, owners of transportation facilities, warehouse owners, owners of transient-prone outdoor lighting, and owners of transient-prone indoor lighting in heavy industrial facilities. DOE adjusted particular inputs to the LCC model to reflect conditions faced by the identified subgroups. For utilities, DOE assumed that maintenance costs would be higher than average maintenance costs because utilities have to maintain more equipment than the other subgroups do, and that operating costs are lower than average because utilities pay wholesale rates for electricity instead of retail rates. DOE assumed that owners of transportation facilities face higher annual operating hours than the average used in the main LCC analysis. For warehouse owners, DOE assumed lower annual operating hours than average used in the main LCC analysis. DOE assumed that owners of transient-prone outdoor lighting face more frequent surge protection and ballast replacements because of lightning than the average used in the main LCC analysis. Finally, for owners of heavy industrial facilities, DOE assumed that indoor lighting equipment (250 W and 400 W equipment classes only) faced more frequent surge protection and ballast replacements because of voltage transients than the average used in the main LCC analysis.

Table VII.16 through Table VII.27 show the LCC effects and PBPs for identified subgroups that purchase metal halide lamp fixtures. In general, the average LCC savings for the identified subgroups at the considered efficiency levels are significantly different from the average for all customers.

TABLE VII.16—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (INDOOR, MAGNETIC BASELINE): LCC SUBGROUP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average Savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	442.76	444.35	887.11				
1	1	445.70	444.92	890.62	−3.50	100.0	0.0	Never
2, 3	2	454.09	446.85	900.94	−13.82	100.0	0.0	Never
4	3	459.40	477.98	937.38	−50.26	93.7	6.3	Never
5	4	472.80	483.06	955.86	−68.75	98.0	2.0	Never
Subgroup: Transportation Facility Owners								
	Baseline	442.76	979.64	1,422.40				
1	1	445.70	948.60	1,394.30	28.10	0.0	100.0	1.4
2, 3	2	454.09	939.88	1,393.97	28.43	0.0	100.0	4.3
4	3	459.40	923.95	1,383.35	39.05	17.4	82.6	3.8
5	4	472.80	915.84	1,388.64	33.76	20.9	79.1	6.3
Subgroup: Warehouse Owners								
	Baseline	442.76	936.53	1,379.29				
1	1	445.70	906.98	1,352.68	26.61	0.0	100.0	1.5
2, 3	2	454.09	898.53	1,352.62	26.67	0.1	99.9	4.6
4	3	459.40	878.47	1,337.87	41.42	17.4	82.6	3.5
5	4	472.80	870.24	1,343.05	36.25	19.9	80.1	5.9

TABLE VII.17—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (INDOOR, ELECTRONIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average Savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
1, 2, 3, 4	Baseline/3	459.40	477.98	937.38	.....	.....	.....	.....
5	4	472.80	483.06	955.86	−18.49	100.0	0.0	Never
Subgroup: Transportation Facility Owners								
1, 2, 3, 4	Baseline/3	459.40	923.95	1,383.35	.....	.....	.....	.....
5	4	472.80	915.84	1,388.64	−5.29	88.8	11.2	31.9
Subgroup: Warehouse Owners								
1, 2, 3, 4	Baseline/3	459.40	878.47	1,337.87	.....	.....	.....	.....
5	4	472.80	870.24	1,343.05	−5.17	89.5	10.5	30.5

TABLE VII.18—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR, MAGNETIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline ...	793.71	1,536.88	2,330.59	.....	.....	.....	.....
1	1	796.52	1,538.23	2,334.75	−4.16	100.0	0.0	Never
2, 3	2	804.56	1,542.56	2,347.12	−16.52	100.0	0.0	Never
4	3	835.01	1,620.58	2,455.59	−125.00	87.2	12.8	Never
5	4	847.86	1,630.51	2,478.36	−147.77	89.9	10.1	Never
Subgroup: Transportation Facility Owners								
	Baseline ...	793.69	2,195.72	2,989.41	.....	.....	.....	.....
1	1	796.50	2,158.67	2,955.17	34.24	1.6	98.4	1.4
2, 3	2	804.53	2,149.99	2,954.53	34.88	2.9	97.1	4.5
4	3	834.98	2,159.40	2,994.38	−4.98	49.0	51.0	12.0
5	4	847.83	2,152.73	3,000.55	−11.15	51.3	48.7	14.7
Subgroup: Warehouse Owners								
	Baseline ...	793.69	2,195.72	2,989.41	.....	.....	.....	.....
1	1	796.50	2,158.67	2,955.17	34.24	1.6	98.4	1.4
2, 3	2	804.53	2,149.99	2,954.53	34.88	2.9	97.1	4.5
4	3	834.98	2,159.40	2,994.38	−4.98	49.0	51.0	12.0
5	4	847.83	2,152.73	3,000.55	−11.15	51.3	48.7	14.7
Subgroup: Owners of Transient-Prone Outdoor Lighting								
	Baseline ...	793.71	2,179.70	2,973.41	.....	.....	.....	.....
1	1	796.52	2,142.44	2,938.97	34.44	1.8	98.2	1.4
2, 3	2	804.56	2,133.66	2,938.22	35.20	2.9	97.1	4.5
4	3	835.01	2,167.47	3,002.48	−29.07	59.2	40.8	31.3
5	4	847.86	2,163.21	3,011.07	−37.66	62.2	37.8	41.0

TABLE VII.19—EQUIPMENT CLASS 1—70 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR, ELECTRONIC BASELINE): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
1, 2, 3, 4	Baseline/3	835.01	1,620.58	2,455.59				
5	4	847.86	1,630.51	2,478.36	−22.77	100.0	0.0	Never
Subgroup: Transportation Facility Owners								
1, 2, 3, 4	Baseline/3	834.98	2,159.40	2,994.38				
5	4	847.83	2,152.73	3,000.55	−6.17	87.8	12.2	55.8
Subgroup: Warehouse Owners								
1, 2, 3, 4	Baseline/3	834.98	2,159.40	2,994.38				
5	4	847.83	2,152.73	3,000.55	−6.17	87.8	12.2	55.8
Subgroup: Owners of Transient-Prone Outdoor Lighting								
1, 2, 3, 4	Baseline/3	835.01	2,167.47	3,002.48				
5	4	847.86	2,163.21	3,011.07	−8.59	94.9	5.1	161.5

TABLE VII.20—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline ...	483.05	466.08	949.13				
1	1	491.95	468.47	960.43	−11.29	100.0	0.0	Never
2, 3	2	504.68	472.02	976.71	−27.57	100.0	0.0	Never
4	3	503.23	513.09	1,016.31	−67.18	97.0	3.0	Never
5	4	522.45	521.74	1,044.18	−95.05	99.6	0.4	Never
Subgroup: Transportation Facility Owners								
	Baseline ...	483.05	1,636.83	2,119.88				
1	1	491.95	1,603.44	2,095.39	24.49	0.0	100.0	4.1
2, 3	2	504.68	1,587.84	2,092.53	27.35	0.7	99.3	7.0
4	3	503.23	1,521.09	2,024.32	95.56	7.2	92.8	2.4
5	4	522.45	1,515.71	2,038.15	81.73	11.1	88.9	4.6
Subgroup: Warehouse Owners								
	Baseline ...	483.05	1,494.69	1,977.73				
1	1	491.95	1,463.62	1,955.58	22.16	0.0	100.0	4.4
2, 3	2	504.68	1,448.78	1,953.46	24.27	0.8	99.2	7.5
4	3	503.23	1,382.65	1,885.88	91.86	5.5	94.5	2.4
5	4	522.45	1,376.64	1,899.08	78.65	11.2	88.8	4.5

TABLE VII.21—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline ...	808.82	1,406.87	2,215.69				
1	1	817.35	1,411.33	2,228.68	−12.99	100.0	0.0	Never

TABLE VII.21—EQUIPMENT CLASS 2—150 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
2, 3	2	829.54	1,417.89	2,247.43	−31.74	100.0	0.0	Never
4	3	855.36	1,499.15	2,354.52	−138.83	87.1	12.9	Never
5	4	873.77	1,513.42	2,387.18	−171.49	90.7	9.3	Never
Subgroup: Transportation Facility Owners								
	Baseline	808.79	2,679.99	3,488.78				
1	1	817.32	2,644.09	3,461.41	27.37	2.9	97.1	4.5
2, 3	2	829.51	2,628.57	3,458.08	30.70	3.3	96.7	8.1
4	3	855.33	2,581.21	3,436.54	52.23	33.8	66.2	7.5
5	4	873.73	2,578.45	3,452.18	36.60	38.2	61.8	10.3
Subgroup: Warehouse Owners								
	Baseline	808.79	2,679.99	3,488.78				
1	1	817.32	2,644.09	3,461.41	27.37	2.9	97.1	4.5
2, 3	2	829.51	2,628.57	3,458.08	30.70	3.3	96.7	8.1
4	3	855.33	2,581.21	3,436.54	52.23	33.8	66.2	7.5
5	4	873.73	2,578.45	3,452.18	36.60	38.2	61.8	10.3
Subgroup: Owners of Transient-Prone Outdoor Lighting								
	Baseline	808.82	2,671.89	3,480.71				
1	1	817.35	2,635.75	3,453.09	27.62	2.9	97.1	4.5
2, 3	2	829.54	2,620.05	3,449.58	31.13	3.2	96.8	8.1
4	3	855.36	2,608.06	3,463.42	17.29	47.8	52.2	11.8
5	4	873.77	2,608.78	3,482.55	−1.84	52.3	47.7	17.4

TABLE VII.22—EQUIPMENT CLASS 3—250 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	541.05	490.86	1,031.91				
1, 2	1	564.58	498.98	1,063.56	−31.66	100.0	0.0	Never
3	2	581.69	504.93	1,086.62	−54.71	100.0	0.0	Never
4	3	611.57	572.99	1,184.56	−152.65	100.0	0.0	Never
5	4	604.35	569.07	1,173.42	−141.51	99.9	0.1	Never
Subgroup: Transportation Facility Owners								
	Baseline	541.05	2,361.30	2,902.35				
1, 2	1	564.58	2,330.88	2,895.46	6.89	30.2	69.8	13.0
3	2	581.69	2,318.58	2,900.26	2.08	56.2	43.8	16.6
4	3	611.57	2,354.22	2,965.79	−63.44	81.4	18.6	147.2
5	4	604.35	2,340.54	2,944.89	−42.54	70.6	29.4	39.2
Subgroup: Warehouse Owners								
	Baseline	541.05	2,096.87	2,637.92				
1, 2	1	564.58	2,068.76	2,633.35	4.57	39.4	60.6	14.2
3	2	581.69	2,057.12	2,638.80	−0.89	62.7	37.3	17.9
4	3	611.57	2,086.19	2,697.76	−59.84	82.0	18.0	133.3
5	4	604.35	2,074.29	2,678.63	−40.72	72.1	27.9	40.0
Subgroup: Owners of Transient-Prone Indoor Lighting								
	Baseline	541.05	2,125.94	2,666.98				
1, 2	1	564.58	2,097.72	2,662.30	4.68	39.7	60.3	14.1
3	2	581.69	2,086.10	2,667.79	−0.80	63.0	37.0	17.7

TABLE VII.22—EQUIPMENT CLASS 3—250 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
4	3	633.04	2,202.92	2,835.96	−168.97	99.5	0.5	Never
5	4	625.82	2,189.03	2,814.85	−147.86	99.0	1.0	Never

TABLE VII.23 EQUIPMENT CLASS 3—250 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	1,009.40	1,274.00	2,283.40				
1, 2	1	1,031.93	1,286.12	2,318.06	−34.66	100.0	0.0	Never
3	2	1,048.32	1,294.99	2,343.30	−59.91	100.0	0.0	Never
4	3	1,109.44	1,402.28	2,511.72	−228.33	94.7	5.3	Never
5	4	1,102.53	1,396.84	2,499.37	−215.97	93.4	6.6	Never
Subgroup: Transportation Facility Owners								
	Baseline	1,009.36	3,153.36	4,162.72				
1, 2	1	1,031.89	3,124.09	4,155.98	6.74	32.6	67.4	17.4
3	2	1,048.27	3,112.97	4,161.24	1.48	55.2	44.8	22.8
4	3	1,109.39	3,172.98	4,282.37	−119.65	76.4	23.6	326.7
5	4	1,102.47	3,158.11	4,260.58	−97.86	71.2	28.8	135.1
Subgroup: Warehouse Owners								
	Baseline	1,009.36	3,153.36	4,162.72				
1, 2	1	1,031.89	3,124.09	4,155.98	6.74	32.6	67.4	17.4
3	2	1,048.27	3,112.97	4,161.24	1.48	55.2	44.8	22.8
4	3	1,109.39	3,172.98	4,282.37	−119.65	76.4	23.6	326.7
5	4	1,102.47	3,158.11	4,260.58	−97.86	71.2	28.8	135.1
Subgroup: Owners of Transient-Prone Outdoor Lighting								
	Baseline	1,009.40	3,152.36	4,161.76				
1, 2	1	1,031.93	3,122.75	4,154.68	7.08	32.0	68.0	17.3
3	2	1,048.32	3,111.43	4,159.74	2.02	54.7	45.3	22.7
4	3	1,109.44	3,240.29	4,349.73	−187.97	90.0	10.0	Never
5	4	1,102.53	3,224.03	4,326.55	−164.79	86.7	13.3	Never

TABLE VII.24—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost 2012$			Life-cycle cost savings			Median payback period years
		Installed cost	Discounted operating cost	LCC	Average savings 2012$	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	628.50	448.11	1,076.61				
1	1	669.26	463.69	1,132.95	−56.34	100.0	0.0	Never
2, 3	2	686.28	470.18	1,156.45	−79.84	100.0	0.0	Never
4	3	757.01	568.72	1,325.74	−249.13	100.0	0.0	Never
5	4	798.27	592.98	1,391.25	−314.64	100.0	0.0	Never

TABLE VII.24—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Transportation Facility Owners								
	Baseline ...	628.50	3,542.88	4,171.38	.....	.....	.....	.....
1	1	669.26	3,496.08	4,165.34	6.04	46.9	53.1	15.2
2, 3	2	686.28	3,472.11	4,158.39	13.00	38.9	61.1	14.1
4	3	757.01	3,527.12	4,284.13	−112.75	89.5	10.5	Never
5	4	798.27	3,508.32	4,306.59	−135.20	91.9	8.1	166.6
Subgroup: Warehouse Owners								
	Baseline ...	628.50	3,097.26	3,725.76	.....	.....	.....	.....
1	1	669.26	3,053.68	3,722.95	2.82	54.0	46.0	16.1
2, 3	2	686.28	3,031.58	3,717.85	7.91	46.7	53.3	15.0
4	3	757.01	3,077.37	3,834.39	−108.63	92.0	8.0	905.6
5	4	798.27	3,058.66	3,856.92	−131.16	93.8	6.2	151.6
Subgroup: Owners of Transient-Prone indoor Lighting								
	Baseline ...	628.50	3,125.34	3,753.84	.....	.....	.....	.....
1	1	669.26	3,081.43	3,750.69	3.15	53.2	46.8	16.0
2, 3	2	686.28	3,059.14	3,745.42	8.42	45.9	54.1	15.0
4	3	778.48	3,212.60	3,991.09	−237.25	99.6	0.4	Never
5	4	819.73	3,204.61	4,024.35	−270.51	99.7	0.3	Never

TABLE VII.25—EQUIPMENT CLASS 4—400 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline ...	1,077.60	1,039.14	2,116.75	.....	.....	.....	.....
1	1	1,116.64	1,060.17	2,176.81	−60.06	100.0	0.0	Never
2, 3	2	1,132.93	1,068.93	2,201.86	−85.11	100.0	0.0	Never
4	3	1,229.80	1,210.75	2,440.55	−323.80	98.7	1.3	Never
5	4	1,269.31	1,241.30	2,510.61	−393.86	99.6	0.4	Never
Subgroup: Transportation Facility Owners								
	Baseline ...	1,077.56	4,040.60	5,118.16	.....	.....	.....	.....
1	1	1,116.59	3,995.41	5,112.00	6.16	44.6	55.4	19.9
2, 3	2	1,132.88	3,972.13	5,105.01	13.15	38.1	61.9	18.4
4	3	1,229.74	4,053.72	5,283.46	−165.30	80.7	19.3	Never
5	4	1,269.24	4,036.62	5,305.85	−187.69	83.9	16.1	Never
Subgroup: Warehouse Owners								
	Baseline ...	1,077.56	4,040.60	5,118.16	.....	.....	.....	.....
1	1	1,116.59	3,995.41	5,112.00	6.16	44.6	55.4	19.9
2, 3	2	1,132.88	3,972.13	5,105.01	13.15	38.1	61.9	18.4
4	3	1,229.74	4,053.72	5,283.46	−165.30	80.7	19.3	Never
5	4	1,269.24	4,036.62	5,305.85	−187.69	83.9	16.1	Never
Subgroup: Owners of Transient-Prone Outdoor Lighting								
	Baseline ...	1,077.60	4,044.53	5,122.13	.....	.....	.....	.....
1	1	1,116.64	3,998.77	5,115.41	6.72	44.2	55.8	19.9
2, 3	2	1,132.93	3,975.23	5,108.17	13.97	37.6	62.4	18.3
4	3	1,229.80	4,159.95	5,389.75	−267.62	96.3	3.7	Never
5	4	1,269.31	4,150.29	5,419.60	−297.47	97.3	2.7	Never

TABLE VII.26—EQUIPMENT CLASS 5—1000 WATT METAL HALIDE LAMP FIXTURES (INDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	760.82	1,091.41	1,852.22				
	Baseline+DS*							
	Baseline+DS**	810.09	1,258.76	2,068.85	−216.63	100.0	0.0	N/A
	EL1	816.76	1,119.70	1,936.46	−84.23	100.0	0.0	Never
	EL1+DS*	801.78	720.57	1,522.35	329.87	4.0	96.0	1.5
	EL1+DS**	866.04	1,287.05	2,153.09	−300.86	100.0	0.0	Never
	EL2	837.81	1,130.34	1,968.16	−115.93	100.0	0.0	Never
1, 2, 3, 4, 5	EL2+DS*	831.04	735.29	1,566.33	285.90	4.1	95.9	2.7
1, 2, 3, 4, 5	EL2+DS**	887.09	1,297.70	2,184.79	−332.57	100.0	0.0	Never
Subgroup: Transportation Facility Owners								
	Baseline	760.82	9,226.73	9,987.55				
	Baseline+DS*							
	Baseline+DS**	810.09	9,426.57	10,236.67	−249.12	100.0	0.0	N/A
	EL1	816.76	9,153.37	9,970.13	17.41	34.0	66.0	13.7
	EL1+DS*	801.78	7,781.69	8,583.47	1,404.08	0.0	100.0	0.4
	EL1+DS**	866.04	9,353.22	10,219.25	−231.71	99.7	0.3	Never
	EL2	837.81	9,125.67	9,963.48	24.06	33.9	66.1	13.6
1, 2, 3, 4, 5	EL2+DS*	831.04	7,726.91	8,557.95	1,429.60	0.0	100.0	0.7
1, 2, 3, 4, 5	EL2+DS**	887.09	9,325.51	10,212.60	−225.06	99.6	0.4	Never
Subgroup: Warehouse Owners								
	Baseline	760.82	7,821.14	8,581.96				
	Baseline+DS*							
	Baseline+DS**	810.09	7,990.69	8,800.78	−218.83	100.0	0.0	N/A
	EL1	816.76	7,755.53	8,572.29	9.66	45.6	54.4	15.4
	EL1+DS*	801.78	6,584.62	7,386.40	1,195.55	0.0	100.0	0.5
	EL1+DS**	866.04	7,925.08	8,791.12	−209.16	99.7	0.3	Never
	EL2	837.81	7,730.76	8,568.58	13.38	45.5	54.5	15.4
1, 2, 3, 4, 5	EL2+DS*	831.04	6,536.33	7,367.37	1,214.59	0.0	100.0	0.8
1, 2, 3, 4, 5	EL2+DS**	887.09	7,900.31	8,787.40	−205.45	99.6	0.4	Never

*DS = Design Standard prohibits fixtures from containing a probe-start ballast. A percentage of customers in this equipment class will migrate to these fixtures, which are reduced-wattage 875 W systems.

**Design Standard 1000 W pulse-start fixtures. Customers who do not migrate to 875 W systems will choose these 1000 W systems.

TABLE VII.27—EQUIPMENT CLASS 5—1000 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
Subgroup: Utilities								
	Baseline	1,184.66	1,966.58	3,151.25				
	Baseline+DS*							
	Baseline+DS**	1,240.01	2,251.71	3,491.72	−340.47	100.0	0.0	N/A
	EL1	1,238.24	1,995.40	3,233.63	−82.38	100.0	0.0	Never
	EL1+DS*	1,231.53	1,229.54	2,461.07	690.17	4.3	95.7	1.2
	EL1+DS**	1,293.58	2,280.52	3,574.10	−422.86	100.0	0.0	Never
	EL2	1,258.40	2,006.24	3,264.64	−113.39	100.0	0.0	Never
1, 2, 3, 4, 5	EL2+DS*	1,259.55	1,244.54	2,504.08	647.16	5.4	94.6	2.1
1, 2, 3, 4, 5	EL2+DS**	1,313.74	2,291.37	3,605.11	−453.86	100.0	0.0	Never
Subgroup: Transportation Facility Owners								
	Baseline	1,184.62	9,152.48	10,337.10				
	Baseline+DS*							
	Baseline+DS**	1,239.95	9,435.92	10,675.88	−338.78	100.0	0.0	N/A
	EL1	1,238.18	9,081.54	10,319.72	17.37	30.4	69.6	17.0

TABLE VII.27—EQUIPMENT CLASS 5—1000 WATT METAL HALIDE LAMP FIXTURES (OUTDOOR): LCC AND PBP RESULTS—Continued

Trial standard level	Efficiency level	Life-cycle cost *2012$*			Life-cycle cost savings			Median payback period *years*
		Installed cost	Discounted operating cost	LCC	Average savings *2012$*	Percent of customers that experience		
						Net cost	Net benefit	
	EL1+DS*	1,231.48	7,497.64	8,729.12	1,607.97	0.1	99.9	0.5
	EL1+DS**	1,293.52	9,364.98	10,658.50	−321.40	99.7	0.3	Never
	EL2	1,258.34	9,054.76	10,313.10	24.00	30.3	69.7	17.0
1, 2, 3, 4, 5	EL2+DS*	1,259.49	7,445.67	8,705.16	1,631.94	1.6	98.4	0.8
1, 2, 3, 4, 5	EL2+DS**	1,313.68	9,338.20	10,651.88	−314.78	99.7	0.3	Never
Subgroup: Warehouse Owners								
	Baseline	1,184.62	9,152.48	10,337.10				
	Baseline+DS*							
	Baseline+DS**	1,239.95	9,435.92	10,675.88	−338.78	100.0	0.0	N/A
	EL1	1,238.18	9,081.54	10,319.72	17.37	30.4	69.6	17.0
	EL1+DS*	1,231.48	7,497.64	8,729.12	1,607.97	0.1	99.9	0.5
	EL1+DS**	1,293.52	9,364.98	10,658.50	−321.40	99.7	0.3	Never
	EL2	1,258.34	9,054.76	10,313.10	24.00	30.3	69.7	17.0
1, 2, 3, 4, 5	EL2+DS*	1,259.49	7,445.67	8,705.16	1,631.94	1.6	98.4	0.8
1, 2, 3, 4, 5	EL2+DS**	1,313.68	9,338.20	10,651.88	−314.78	99.7	0.3	Never
Subgroup: Owners of Transient-Prone Outdoor Lighting								
	Baseline	1,184.66	9,169.03	10,353.69				
	Baseline+DS*							
	Baseline+DS**	1,240.01	9,454.15	10,694.16	−340.47	100.0	0.0	N/A
	EL1	1,238.24	9,097.27	10,335.50	18.19	29.8	70.2	16.9
	EL1+DS*	1,231.53	7,511.15	8,742.68	1,611.01	0.1	99.9	0.5
	EL1+DS**	1,293.58	9,382.40	10,675.98	−322.29	99.7	0.3	Never
	EL2	1,258.40	9,070.18	10,328.57	25.12	29.7	70.3	16.8
1, 2, 3, 4, 5	EL2+DS*	1,259.55	7,458.67	8,718.22	1,635.47	1.8	98.2	0.8
1, 2, 3, 4, 5	EL2+DS**	1,313.74	9,355.30	10,669.04	−315.35	99.7	0.3	Never

* DS = Design Standard prohibits fixtures from containing a probe-start ballast. A percentage of customers in this equipment class will migrate to these fixtures, which are reduced-wattage 875 W systems.
** Design Standard 1000 W pulse-start fixtures. Customers who do not migrate to 875 W systems will choose these 1000 W systems.

c. Rebuttable Presumption Payback

As discussed in section IV.D.2, EPCA establishes a rebuttable presumption that, in essence, an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. (42 U.S.C. 6295(o)(2)(B)(iii)) DOE calculated a rebuttable presumption payback period for each TSL to determine whether DOE could presume that a standard at that level is economically justified. Table VII.28 shows the rebuttable-presumption payback periods for the fixture TSLs. Because only a single, average value is necessary for establishing the rebuttable-presumption payback period, rather than using distributions for input values, DOE used discrete values. As required by EPCA, DOE based the calculation on the assumptions in the DOE test procedures for microwave ovens. (42 U.S.C. 6295(o)(2)(B)(iii)) As a result, DOE calculated a single rebuttable presumption payback value, and not a distribution of payback periods, for each TSL.

TABLE VII.28—FIXTURE EFFICIENCY LEVELS WITH A REBUTTABLE PAYBACK PERIOD OF LESS THAN THREE YEARS

Equipment class	Efficiency level	Mean payback period *years*
70 W (indoor, magnetic baseline)	1	1.3
70 W (outdoor, magnetic baseline)	1	1.4
1000 W (indoor)	1 + DS*	0.4
	2 + DS*	0.7
1000 W (outdoor)	1 + DS*	0.6
	2 + DS*	1.0

* DS = Design standard requiring that all fixtures shall not contain a probe-start ballast.

All the fixture efficiency levels in the LCC and PBP results tables have rebuttable-presumption payback periods of less than 3 years. DOE believes that the rebuttable-presumption payback period criterion (*i.e.*, a limited payback period) is not sufficient for determining economic justification. Therefore, DOE has considered a full range of impacts,

including those to consumers, manufacturers, the Nation, and the environment. Section IV of this rulemaking provides a complete discussion of how DOE considered the range of impacts to select the standards in today's final rule.

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of new and amended energy conservation standards on manufacturers of MHLFs and ballasts. The section below describes the expected impacts on manufacturers at each TSL. Chapter 13 of this final rule TSD explains the analysis in further detail.

a. Industry Cash-Flow Analysis Results

The tables below depict the financial impacts (represented by changes in INPV) of new and amended energy conservation standards on manufacturers as well as the conversion costs that DOE estimates manufacturers would incur at each TSL. DOE reports the impacts on manufacturers of MHLFs and ballasts separately. Within each industry, DOE presents the results for all equipment classes in one group because most equipment classes are generally made by the same manufacturers. To evaluate the range of cash-flow impacts on the MHLF and ballast industries, DOE modeled four different scenarios using different assumptions for markups and shipments that correspond to the range of anticipated market responses to new and amended standards. Each scenario results in a unique set of cash flows and corresponding INPV at each TSL.

DOE presents two of these shipment and markup scenario combinations in the following section. These scenarios represent the upper and lower bounds of market responses that DOE anticipates could occur in the standards case. The INPV results presented refer to the difference in industry value between the base case and the standards case that result from the sum of discounted cash flows from the base year (2014) through the end of the analysis period. The cash-flow results presented refer to the difference in cash flow between the base case and the standards case in 2016, the year before compliance is required. This figure represents the size of the required conversion costs relative to the cash flow generated by the industry in the absence of new and amended energy conservation standards.

Cash-Flow Analysis Results by TSL for Metal Halide Ballasts

To assess the upper (less severe) end of the range of potential impacts on MH ballast manufacturers, DOE modeled a flat markup scenario. The flat markup scenario assumes that in the standards case, manufacturers would be able to pass along all the higher production costs required for more efficient equipment to their customers. Specifically, the industry would be able to maintain its average base case gross margin, as a percentage of revenue, despite the higher production costs in the standards case. In general, the larger the equipment price increases, the less likely manufacturers are to achieve the cash flow from operations calculated in this scenario because it is less likely that manufacturers would be able to fully markup these larger cost increases.

DOE also used the high-shipment scenario to assess the upper bound of impacts. Under the high-shipment scenario, base case shipments of MHLFs decrease at a slower rate over the analysis period compared to the low-shipment scenario. The combination of the flat markup and high-shipment scenario provides the best conditions for cash flow generation than any other combination analyzed by DOE in the MIA. In this scenario, manufacturers experience higher annual shipment volumes and have the ability to preserve their base case gross margins. Thus, this combination of scenarios yields the greatest modeled industry profitability.

To assess the lower (more severe) end of the range of potential impacts on the MH ballast industry, DOE modeled the preservation of operating profit markup scenario. This scenario represents the lower end of the range of potential impacts on manufacturers because no additional operating profit is earned on the higher production costs, eroding profit margins as a percentage of total revenue.

DOE also used the low-shipment scenario to assess the lower bound of impacts. Under the low-shipment scenario, MHLF shipments decrease at a faster rate over the analysis period compared to the high-shipment scenario. The combination of the preservation of operating profit markup and low-shipment scenario most restricts manufacturers' ability to pass on costs to customers and assumes the lowest level of shipments. Thus, this combination of scenarios estimates the largest manufacturer impacts.

TABLE VII.29—MANUFACTURER IMPACT ANALYSIS FOR METAL HALIDE BALLASTS—FLAT MARKUP AND HIGH-SHIPMENT SCENARIO

	Units	Base case	Trial standard level				
			1	2	3	4	5
INPV	(2012$ millions)	74	71	74	75	83	89
Change in INPV	(2012$ millions)		(3.1)	(0.4)	0.6	9.6	15.0
	(%)		−4.2	−0.5	0.8	12.9	20.3
Product Conversion Costs	(2012$ millions)		11	12	12	16	20
Capital Conversion Costs	(2012$ millions)		9	10	11	4	5
Total Conversion Costs	(2012$ millions)		21	22	23	21	24

TABLE VII.30—MANUFACTURER IMPACT ANALYSIS FOR METAL HALIDE BALLASTS—PRESERVATION OF OPERATING PROFIT MARKUP AND LOW-SHIPMENT SCENARIO

	Units	Base case	Trial standard level				
			1	2	3	4	5
INPV	(2012$ millions)	67	50	49	48	51	48
Change in INPV	(2012$ millions)		(16.5)	(17.9)	(19.0)	(16.2)	(19.0)
	(%)		−24.6	−26.7	−28.3	−24.1	−28.3

TABLE VII.30—MANUFACTURER IMPACT ANALYSIS FOR METAL HALIDE BALLASTS—PRESERVATION OF OPERATING PROFIT MARKUP AND LOW-SHIPMENT SCENARIO—Continued

	Units	Base case	Trial standard level				
			1	2	3	4	5
Product Conversion Costs	(2012$ millions)		11	12	12	16	20
Capital Conversion Costs	(2012$ millions)		9	10	11	4	5
Total Conversion Costs	(2012$ millions)		21	22	23	21	24

TSL 1 is baseline for two of the 12 equipment classes (1500 W indoor and outdoor), EL1 for eight of the 12 equipment classes (70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor), and EL2 for the remaining two equipment classes (1000 W indoor and outdoor). At TSL 1, DOE estimates impacts on INPV range from −$3.1 million to −$16.5 million, or a change in INPV of −4.2 percent to −24.6 percent. At TSL 1, industry free cash flow (operating cash flow minus capital expenditures) is estimated to decrease by approximately 105 percent to −$0.4 million, compared to the base case value of $7.2 million in 2016.

Impacts on INPV range from slightly negative to moderately negative at TSL 1. TSL 1 requires the use of more efficient magnetic ballasts for the 70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, 400 W indoor and outdoor, and 1000 W indoor and outdoor equipment classes. DOE projects that in 2017, 92 percent of 70 W indoor shipments, 13 percent of 150 W indoor shipments, 16 percent of 250 W indoor shipments, seven percent of 400 W indoor shipments, one percent of 1000 W indoor shipments, 100 percent of 1500 W indoor shipments, 40 percent of 70 W outdoor shipments, two percent of 150 W outdoor shipments, 10 percent of 250 W outdoor shipments, one percent of 1000 W outdoor shipments, and 100 percent of 1500 W outdoor shipments would meet TSL 1 or higher in the base case. No shipments from the 400 W outdoor equipment class would meet TSL 1 or higher in the base case in 2017.

Conversion costs are expected to be moderate at TSL 1. DOE expects ballast manufacturers to incur $11 million in product conversion costs for model redesigns and testing and $9 million in capital conversion costs for equipment such as stamping dies to process more efficient steel cores.

At TSL 1, the shipment-weighted average MPC increases by 29 percent relative to the base case MPC. Under the flat markup scenario, manufacturers are able to fully pass on this cost increase to customers under this scenario. Additionally, under the high-shipment scenario, shipments are 130 percent higher than shipments under the low-shipment scenario in the last year of the analysis period. Thus, manufacturers generate the most revenue under this combination (flat markup and high-shipment) of scenarios. The fairly large $21 million in conversion costs estimated at TSL 1 outweigh the moderate MPC increase even when applied to the larger quantity of shipments of the high-shipment scenario, resulting in slightly negative INPV impacts at TSL 1 under the flat markup and high-shipment scenarios.

Under the preservation of operating profit markup scenario, manufacturers earn the same operating profit as they would in the base case in 2018, however, manufacturers do not earn additional profit from their investments. In this scenario, the 29 percent MPC increase is outweighed by a lower average markup of 1.43 (compared to the flat markup scenario markup of 1.47) and $21 million in conversion costs, resulting in greater negative impacts at TSL 1. The low-shipment scenario exacerbates these impacts because the base case INPV (the figure against which the absolute change in INPV is compared) is 10 percent lower than the base case INPV in the high-shipment scenario.

TSL 2 is baseline for two of the 12 equipment classes (1500 W indoor and outdoor), EL1 for two of the 12 equipment classes (250 W indoor and outdoor), and EL2 for the remaining eight equipment classes (70 W indoor and outdoor, 150 W indoor and outdoor, 400 W indoor and outdoor, and 1000 W indoor and outdoor). At TSL 2, DOE estimates impacts on INPV to range from −$0.4 million to −$17.9 million, or a change in INPV of −0.5 percent to −26.7 percent. At this level, industry free cash flow is estimated to decrease by approximately 114 percent to −$1.0 million, compared to the base case value of $7.2 million in 2016.

For several equipment classes TSL 2 is the highest efficiency level the engineering analysis assumes manufacturers can meet with magnetic ballasts. DOE projects that in 2017, 89 percent of 70 W indoor shipments, ten percent of 150 W indoor shipments, 16 percent of 250 W indoor shipments, seven percent of 400 W indoor shipments, one percent of 1000 W indoor shipments, 100 percent of 1500 W indoor shipments, 10 percent of 250 W outdoor shipments, one percent of 1000 W outdoor shipments, and 100 percent of 1500 W outdoor shipments would meet TSL 2 or higher in the base case. No shipments from the 70 W outdoor, 150 W outdoor, or 400 W outdoor equipment classes would meet TSL 2 or higher in the base case in 2017. At TSL 2, product conversion costs slightly rise to $12 million and capital conversion costs slightly rise to $10 million as manufacturers need to purchase additional equipment and tooling to upgrade magnetic production lines.

At TSL 2, the shipment-weighted average MPC increases 38 percent over the base case MPC. In flat markup scenario, INPV impacts are slightly negative because the $22 million in conversion costs outweigh the manufacturers' ability to pass on the higher equipment costs to customers. Under the preservation of operating profit markup scenario, the 38 percent MPC increase is outweighed by a lower average markup of 1.42 and $22 million in conversion costs, resulting in negative INPV impacts at TSL 2.

TSL 3 is baseline for two of the 12 equipment classes (1500 W indoor and outdoor) and EL2 for the remaining ten equipment classes (70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, 400 W indoor and outdoor, and 1000 W indoor and outdoor). At TSL 3, DOE estimates impacts on INPV to range from $0.6 million to −$19.0 million, or a change in INPV of 0.8 percent to −28.3 percent. At this level, industry free cash flow is estimated to decrease by approximately 120 percent to −$1.5 million, compared to the base case value of $7.2 million in 2016.

TSL 3 is the highest efficiency level the engineering analysis assumes

manufacturers can meet with magnetic ballasts for all equipment classes. DOE projects that in 2017, 89 percent of 70 W indoor shipments, ten percent of 150 W indoor shipments, 12 percent of 250 W indoor shipments, seven percent of 400 W indoor shipments, one percent of 1000 W indoor shipments, 100 percent of 1500 W indoor shipments, one percent of 1000 W outdoor shipments, and 100 percent of 1500 W outdoor shipments would meet TSL 3 or higher in the base case. No shipments from the 70 W outdoor, 150 W outdoor, 250 W outdoor, or 400 W outdoor equipment classes would meet TSL 3 or higher in 2016 in the base case in 2017. DOE expects product conversion costs to remain constant at $12 million and capital conversion costs to increase slightly to $11 million.

At TSL 3 the shipment-weighted average MPC increases 42 percent over the base case MPC. In the flat markup scenario, the additional revenues earned from passing on these higher MPC costs outweigh the $23 million in conversion costs and higher working capital requirements, resulting in slightly positive INPV impacts. Under the preservation of operating profit markup scenario, the 42 percent MPC increase is outweighed by a lower average markup of 1.41 and $23 million in conversion costs, resulting in INPV results remaining negative at TSL 3.

TSL 4 is EL1 for two equipment classes (1500 W indoor and outdoor), EL2 for two equipment classes (1000 W indoor and outdoor), and EL3 for the remaining eight equipment classes (70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor). At TSL 4, DOE estimates impacts on INPV to range from $9.6 million to −$16.2 million, or a change in INPV of 12.9 percent to −24.1 percent. At this level, industry free cash flow is estimated to decrease by approximately 94 percent to $0.5 million, compared to the base case value of $7.2 million in 2016.

The technology changes from TSL 3 to TSL 4 are that manufacturers must now use now electronic ballasts for the 70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor equipment classes at TSL 4. DOE projects that in 2017, 89 percent of 70 W indoor shipments, 10 percent of 150 W indoor shipments, 12 percent of 250 W indoor shipments, seven percent of 400 W indoor shipments, one percent of 1000 W indoor shipments, six percent of 1500 W indoor shipments, one percent of 1000 W outdoor shipments, and four percent of 1500 W outdoor shipments would meet TSL 4 or higher in the base case. No shipments of the 70 W outdoor, 150 W outdoor, 250 W outdoor, or 400 W outdoor equipment classes would meet TSL 4 or higher in the base case in 2017. Total conversion costs decrease from $23 million at TSL 3 to $21 million at TSL 4, because of the flexibility of electronic ballast production within the lighting manufacturing industry.

At TSL 4, the shipment-weighted average MPC increases 63 percent over the base case MPC. In the flat markup scenario, the additional revenues earned from passing on these higher MPC costs outweigh the $21 million in conversion costs, resulting in moderately positive impacts on INPV. Under the preservation of operating profit markup scenario, the MPC increase is outweighed by a lower average markup of 1.40 and $21 million in conversion costs, resulting in INPV results remaining negative at TSL 4.

TSL 5 is EL2 for four of the 12 equipment classes (1000 W indoor and outdoor and 1500 W indoor and outdoor) and EL4 for the remaining eight equipment classes (70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor). At TSL 5, DOE estimates impacts on INPV to range from $15.0 million to −$19.0 million, or a change in INPV of 20.3 percent to −28.3 percent. At this level, industry free cash flow is estimated to decrease by approximately 109 percent to −$0.6 million, compared to the base case value of $7.2 million in 2016.

TSL 5 is max tech for all equipment classes. DOE projects that in 2017, one percent of 70 W indoor shipments, one percent of 1000 W indoor shipments, and one percent of 1000 W outdoor shipments will meet TSL 5 in the base case. No shipments of any of the other equipment classes will meet TSL 5 in the base case in 2017. As a result, product conversion costs increase to $24 million because of the need to redesign and test additional models. However, capital conversion costs remain fairly low at $5 million due to the flexibility of electronic ballast production.

At TSL 5, the shipment-weighted average MPC increases 82 percent over the base case MPC. In the flat markup scenario the additional revenues earned from passing on these higher MPC costs outweigh the increased conversion costs of $24 million, resulting in a moderately positive impact on INPV. Under the preservation of operating profit markup scenario, the MPC increase is outweighed by a lower average markup of 1.39 and $24 million in conversion costs, resulting in INPV results remaining negative at TSL 5.

Cash Flow Analysis Results by TSL for Metal Halide Lamp Fixtures

DOE incorporated the same scenarios to represent the upper and lower bounds of industry impacts for MHLFs as for MH ballasts: the flat markup scenario with the high-shipment scenario and the preservation of operating profit markup scenario with the low-shipment scenario. Note that the TSLs below represent the same sets of efficiency levels as discussed in the previous section in the description of impacts on MH ballast manufacturers.

TABLE VII.31—MANUFACTURER IMPACT ANALYSIS FOR METAL HALIDE LAMP FIXTURES—FLAT MARKUP AND HIGH-SHIPMENT SCENARIO

	Units	Base case	Trial standard level				
			1	2	3	4	5
INPV	(2012$ millions)	379	408	418	423	418	408
Change in INPV	(2012$ millions)		28.4	38.3	43.4	38.6	29.1
	(%)		7.5	10.1	11.4	10.2	7.7
Product Conversion Costs	(2012$ millions)		3	3	3	45	62
Capital Conversion Costs	(2012$ millions)		0	0	0	32	50
Total Conversion Costs	(2012$ millions)		3	3	3	77	112

TABLE VII.32—MANUFACTURER IMPACT ANALYSIS FOR METAL HALIDE LAMP FIXTURES—PRESERVATION OF OPERATING PROFIT MARKUP AND LOW-SHIPMENT SCENARIO

	Units	Base case	Trial standard level				
			1	2	3	4	5
INPV	(2012$ millions)	346	342	342	342	285	257
Change in INPV	(2012$ millions)		(3.6)	(3.6)	(3.6)	(60.4)	(88.6)
	(%)		−1.0	−1.0	−1.1	−17.5	−25.6
Product Conversion Costs	(2012$ millions)		3	3	3	45	62
Capital Conversion Costs	(2012$ millions)		0	0	0	32	50
Total Conversion Costs	(2012$ millions)		3	3	3	77	112

At TSL 1, DOE estimates impacts on INPV to range from $28.4 million to −$3.6 million, or a change in INPV of 7.5 percent to −1.0 percent. At TSL 1, industry free cash flow is estimated to decrease by approximately 3 percent to $38.3 million, compared to the base case value of $39.3 million in 2016.

DOE expects minimal conversion costs for fixture manufacturers at TSL 1. Fixture manufacturers would incur $3 million in product conversion costs for the testing of redesigned ballasts. Because the stack height of magnetic ballasts is not expected to change in response to the standards, fixture manufacturers would not incur any capital conversion costs at efficiency levels that can be met with magnetic ballast such as TSL 1.

At TSL 1, the shipment-weighted average MPC increases by 11 percent from the base case MPC. In the flat markup scenario manufacturers maximize revenue since they are able to fully pass on this cost increase to customers. The slight price increase applied to a large quantity of shipments outweighs the impact of the $3 million in conversion costs for TSL 1, resulting in positive impacts at TSL 1 under the flat markup and high-shipment scenarios.

Under the preservation of operating profit markup scenario a lower average markup of 1.54 (compared to the flat manufacturer markup of 1.58) and $3 million in conversion cost results in a slightly negative impacts at TSL 1. The low-shipment scenario exacerbates these impacts because the base case INPV (the figure against which the absolute change in INPV is compared) is 10 percent lower than the base case INPV in the high-shipment scenario.

At TSL 2, DOE estimates impacts on INPV to range from $38.3 million to −$3.6 million, or a change in INPV of 10.1 percent to −1.0 percent. At this level, industry free cash flow is estimated to decrease by approximately 3 percent to $38.3 million, compared to the base case value of $39.3 million in 2016.

At TSL 2, the shipment-weighted average MPC increases 15 percent over the base case MPC. In the flat markup scenario the additional revenues earned from passing on these higher MPC costs outweigh the fairly low conversion costs of $3 million, resulting in a positive impact on INPV. Under the preservation of operating profit markup scenario, the MPC increase is outweighed by a lower average markup of 1.53 and $3 million in conversion costs, resulting in slightly negative INPV results at TSL 2.

At TSL 3, DOE estimates impacts on INPV to range from $43.4 million to −$3.6 million, or a change in INPV of 11.4 percent to −1.1 percent. At this level, industry free cash flow is estimated to decrease by approximately 3 percent to $38.3 million, compared to the base case value of $39.3 million in 2016. At TSL 3, the shipment-weighted average MPC increases 16 percent over the base case MPC. In the flat markup scenario the additional revenues earned from passing on these higher MPC costs outweigh the fairly low conversion costs of $3 million, resulting in a positive impact on INPV. Under the preservation of operating profit markup scenario, the MPC increase is outweighed by a lower average markup of 1.53 and $3 million in conversion costs, resulting in slightly negative INPV results at TSL 3.

At TSL 4, DOE estimates impacts on INPV to range from $38.6 million to −$60.4 million, or a change in INPV of 10.2 percent to −17.5 percent. At this level, industry free cash flow is estimated to decrease by approximately 72 percent to $10.9 million, compared to the base case value of $39.3 million in 2016.

The technology changes from TSL 3 to TSL 4 are that manufacturers must use electronic ballasts to meet the required efficiencies for the 70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor equipment classes at TSL 4. This increases the product conversion costs from $3 million at TSL 3 to $45 million at TSL 4 and increases the capital conversion costs from zero at TSL 3 to $32 million at TSL 4.

At TSL 4, the shipment-weighted average MPC increases 44 percent over the base case MPC. In the flat markup scenario the additional revenue earned from passing on these higher MPC costs outweigh the increased conversion costs of $77 million, resulting in a positive impact on INPV at TSL 4. Under the preservation of operating profit markup scenario the MPC increase is outweighed by a lower average markup of 1.48 and $77 million in conversion costs, resulting in moderately negative INPV impacts at TSL 4.

At TSL 5, DOE estimates impacts on INPV to range from $29.1 million to −$88.6 million, or a change in INPV of 7.7 percent to −25.6 percent. At this level, industry free cash flow is estimated to decrease by approximately 107 percent to −$2.8 million, compared to the base case value of $39.3 million in 2016.

At TSL 5, product conversion costs again significantly increase to $62 million as manufacturers must redesign all equipment classes to accommodate the most efficient electronic ballasts. Capital conversion costs also significantly increase to $50 million because of the need for additional equipment and tooling, such as new castings to incorporate thermal protection in the 70 W indoor and outdoor, 150 W indoor and outdoor, 250 W indoor and outdoor, and 400 W indoor and outdoor equipment classes.

At TSL 5, the shipment-weighted average MPC increases 51 percent over the base case MPC. In the flat markup scenario the additional revenues earned from passing on these higher MPC costs outweigh the much larger conversion costs of $112 million, resulting in a positive impact on INPV. Under the preservation of operating profit markup scenario, the MPC increase is outweighed by a lower average markup of 1.47 and $112 million in conversion

costs, resulting in significantly negative INPV impacts at TSL 5.

b. Impacts on Employment

DOE quantitatively assessed the impacts of potential new and amended energy conservation standards on direct employment. DOE used the GRIM to estimate the domestic labor expenditures and number of domestic production workers in the base case and at each TSL from 2014 to 2046. DOE used statistical data from the U.S. Census Bureau's 2009 Annual Survey of Manufacturers (ASM), the results of the engineering analysis, and interviews with manufacturers to determine the inputs necessary to calculate industry-wide labor expenditures and domestic employment levels. Labor expenditures involved with the manufacture of the equipment is a function of the labor intensity of the equipment, the sales volume, and an assumption that wages remain fixed in real terms over time.

In the GRIM, DOE used the labor content of the equipment and the manufacturing production costs to estimate the annual labor expenditures in the industry. DOE used Census data and interviews with manufacturers to estimate the portion of the total labor expenditures that is attributable to domestic labor.

The production worker estimates in this section cover only workers up to the line-supervisor level who are directly involved in fabricating and assembling equipment within an OEM facility. Workers performing services that are closely associated with production operations, such as material handing with a forklift, are also included as production labor. DOE's estimates account for only production workers who manufacture the specific equipment covered by this rulemaking. For example, a worker on a fluorescent lamp ballast line would not be included with the estimate of the number of MHLF or MH ballast workers.

The employment impacts shown in the tables below represent the potential production employment that could result following new and amended energy conservation standards. The upper bound of the results estimates the maximum change in the number of production workers that could occur after compliance with new and amended energy conservation standards when assuming that manufacturers continue to produce the same scope of covered equipment in the same production facilities. It also assumes that domestic production does not shift to lower labor-cost countries. Because there is a real risk of manufacturers evaluating sourcing decisions in response to new and amended energy conservation standards, the lower bound of the employment results includes the estimated total number of U.S. production workers in the industry who could lose their jobs if all existing production were moved outside of the United States. While the results present a range of employment impacts following 2017, the sections below also include qualitative discussions of the likelihood of negative employment impacts at the various TSLs. Finally, the employment impacts shown are independent of the employment impacts from the broader U.S. economy, which are documented in chapter 14 of this final rule TSD.

Employment Impacts for Metal Halide Ballasts

Based on 2009 ASM data and interviews with manufacturers, DOE estimates that less than 30 domestic production workers would be involved in manufacturing MH ballasts in 2017, as the vast majority of MH ballasts are manufactured abroad. DOE's view is that manufacturers could face moderate positive impacts on domestic employment levels because increasing equipment costs at each TSL would result in higher labor expenditures per unit, causing manufacturers to hire more workers to meet demand for MH ballasts, assuming that production remains in domestic facilities. Many manufacturers, however, do not expect a significant change in total employment at their facilities. Although manufacturers are concerned that higher prices for MH ballasts will drive customers to alternate technologies, most manufacturers offer these alternate technologies and can shift their employees from MH ballast production to production of other technologies in their facilities. Most manufacturers believe that domestic employment will only be significantly adversely affected if customers shift to foreign imports, causing the total lighting market share of the major domestic manufacturers to decrease.

Employment Impacts for Metal Halide Lamp Fixtures

Using 2009 ASM data and interviews with manufacturers, DOE estimates that approximately 60 percent of the MHLFs sold in the United States are manufactured domestically. With this assumption, DOE estimates that in the absence of new and amended energy conservation standards, there would be approximately 340 domestic production workers involved in manufacturing MHLFs in 2017. Table VII.33 and Table VII.34 show the range of the impacts of potential new and amended energy conservation standards on U.S. production workers in the MHLF industry.

TABLE VII.33—POTENTIAL CHANGES IN THE TOTAL NUMBER OF DOMESTIC METAL HALIDE LAMP FIXTURE PRODUCTION WORKERS IN 2017

[Flat markup and high-shipment scenario]

Base case		Trial standard level				
		1	2	3	4	5
Total Number of Domestic Production Workers in 2017 (without changes in production locations)	345	393	408	415	419	440
Potential Changes in Domestic Production Workers in 2017*		48 – (345)	63 – (345)	70 – (345)	74 – (345)	95 – (345)

* DOE presents a range of potential employment impacts. Numbers in parentheses indicate negative numbers.

TABLE VII.34—POTENTIAL CHANGES IN THE TOTAL NUMBER OF DOMESTIC METAL HALIDE LAMP FIXTURE PRODUCTION WORKERS IN 2017

[Preservation of operating profit markup and low-shipment scenario]

Base case		Trial standard level				
		1	2	3	4	5
Total Number of Domestic Production Workers in 2017 (without changes in production locations)	339	386	401	408	412	432
Potential Changes in Domestic Production Workers in 2017*	.....	47 – (339)	62 – (339)	69 – (339)	73 – (339)	93 – (339)

At the upper end of the range, all examined TSLs show moderate positive impacts on domestic employment levels. The increasing equipment cost at each higher TSL would result in higher labor expenditures per unit, causing manufacturers to hire more workers to meet demand levels of MHLFs, assuming that production remains in domestic facilities. Many manufacturers, however, do not expect a significant change in total employment at their facilities. Although manufacturers are concerned that higher prices for MHLFs will drive customers to alternate technologies, most manufacturers offer these alternate technologies and can shift their employees from MHLF production to production of other technologies in their facilities. As with MH ballast manufacturers, most MHLF manufacturers believe that domestic employment will only be significantly adversely affected if customers shift to foreign imports, causing the total lighting market share of the major domestic manufacturers to decrease. Because of the potentially high cost of shipping MHLFs from overseas, many manufacturers believe that this shift is unlikely to occur, especially for the higher wattage MHLFs. This is particularly true for the significant portion of the market served by small manufacturers, for whom the per-unit shipping costs of sourcing products would be even greater because of the lower volumes that they sell.

Based on the above, DOE does not expect the adopted energy conservation standards for MHLFs, at TSL 2, to have a significant negative impact on direct domestic employment levels. DOE notes that domestic employment levels could be negatively affected in the event that small fixture businesses choose to exit the market due to standards. However, discussions with small manufacturers indicated that most small businesses will be able to adapt to new and amended regulations at the adopted standards. The impacts on small businesses are discussed in section VIII.B.

c. Impacts on Manufacturing Capacity

Both MHLF and ballast manufacturers stated that they do not anticipate any capacity constraints at efficiency levels that can be met with magnetic ballasts, which are the efficiency levels adopted for all equipment classes in today's final rule. If the production of higher-efficiency magnetic ballasts decreases the throughput on production lines, manufacturers stated that they would be able to add shifts on existing lines and maintain capacity.

At efficiency levels that require electronic ballasts, however, manufacturers are concerned about the current worldwide shortage of electrical components. The components most affected by this shortage are high-efficiency parts, for which demand would increase even further following new and amended energy conservation standards. The increased demand could exacerbate the component shortage, thereby impacting manufacturing capacity in the near term, according to manufacturers. However, there are no equipment classes requiring electronic ballasts in today's final rule. Therefore, DOE does not anticipate a significant increase in demand for electric components due to today's energy conservation standards. While DOE recognizes that the premium component shortage is currently a significant issue for manufacturers, DOE views it as a relatively short-term phenomenon to which component suppliers will ultimately adjust. According to several manufacturers, suppliers have the ability to ramp up production to meet MH ballast component demand by the compliance date of new and amended standards, but those suppliers have hesitated to invest in additional capacity due to economic uncertainty and skepticism about the sustainability of demand. The state of the macroeconomic environment through 2017 will likely affect the duration of the premium component shortage. Mandatory standards, however, could create more certainty for suppliers about the eventual demand for these components. Additionally, the premium components at issue are not new technologies; rather, they have simply not historically been demanded in large quantities by MH ballast manufacturers.

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop an industry cash-flow estimate may not be adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche equipment manufacturers, and manufacturers exhibiting cost structures substantially different from the industry average could be affected disproportionately. DOE analyzed the impacts to small businesses in section VIII.B and did not identify any other adversely impacted subgroups for MHLFs or ballasts for this rulemaking based on the results of the industry characterization.

e. Cumulative Regulatory Burden

While any one regulation may not impose a significant burden on manufacturers, the combined effects of recent or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

During previous stages of this rulemaking, DOE identified a number of requirements, in addition to new and

amended energy conservation standards for MHLFs, that manufacturers will face for products and equipment they manufacture approximately three years prior to and three years after the compliance date of the new and amended standards. The following section briefly addresses comments DOE received with respect to cumulative regulatory burden and summarizes other key related concerns that manufacturers raised during interviews and submitted comments.

Several manufacturers expressed concern about the overall volume of DOE energy conservation standards with which they must comply. Most MHLF manufacturers also make a full range of lighting products and share engineering and other resources with these other internal manufacturing divisions for different products, including certification testing for regulatory compliance.

DOE discusses these and other requirements in chapter 13 of this final rule TSD. DOE takes into account the cost of compliance with other published Federal energy conservation standards in weighing the benefits and burdens of today's rulemaking. DOE does not describe the quantitative impacts of standards that have not yet been finalized because any impacts would be speculative. DOE also notes that certain standards, such as ENERGY STAR, are optional for manufacturers.

3. National Impact Analysis

a. Significance of Energy Savings

For each TSL, DOE projected energy savings for metal halide lamp fixtures purchased in the 30-year period that begins in the year 2017, ending in the year 2046. The savings are measured over the entire lifetime of equipment purchased in the 30-year period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the base case. Table VII.35 presents the estimated primary energy savings for each TSL for the low- and high-shipments scenarios, which represent the minimum and maximum energy savings resulting from all the scenarios analyzed. Table VII.36 presents the estimated FFC energy savings for each considered TSL. Chapter 11 of the final rule TSD describes these estimates in more detail.

TABLE VII.35—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046

Trial standard level	Equipment class	National primary energy savings *quads*	
		Low-shipments scenario	High-shipments scenario
1	70 W	0.01	0.01
	150 W	0.02	0.02
	250 W	0.02	0.02
	400 W	0.10	0.13
	1000 W	0.16	0.20
	1500 W	0.00	0.00
	Total	0.30	0.38
2	70 W	0.02	0.02
	150 W	0.04	0.05
	250 W	0.02	0.02
	400 W	0.15	0.19
	1000 W	0.16	0.20
	1500 W	0.00	0.00
	Total	0.38	0.48
3	70 W	0.02	0.02
	150 W	0.04	0.05
	250 W	0.03	0.03
	400 W	0.15	0.19
	1000 W	0.16	0.20
	1500 W	0.00	0.00
	Total	0.39	0.49
4	70 W	0.07	0.09
	150 W	0.10	0.12
	250 W	0.11	0.14
	400 W	0.25	0.31
	1000 W	0.16	0.20
	1500 W	0.00	0.00
	Total	0.69	0.86
5	70 W	0.09	0.11
	150 W	0.11	0.14
	250 W	0.13	0.16
	400 W	0.33	0.41
	1000 W	0.16	0.20
	1500 W	0.00	0.00

TABLE VII.35—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046—Continued

Trial standard level	Equipment class	National primary energy savings *quads*	
		Low-shipments scenario	High-shipments scenario
	Total	0.81	1.02

TABLE VII.36—CUMULATIVE NATIONAL FULL-FUEL-CYCLE ENERGY SAVINGS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046

Trial standard level	Equipment class	National FFC energy savings quads	
		Low-shipments scenario	High-shipments scenario
1	70 W	0.01	0.01
	150 W	0.02	0.02
	250 W	0.02	0.02
	400 W	0.11	0.13
	1000 W	0.16	0.21
	1500 W	0.00	0.00
	Total	0.31	0.39
2	70 W	0.02	0.02
	150 W	0.04	0.05
	250 W	0.02	0.02
	400 W	0.16	0.20
	1000 W	0.16	0.21
	1500 W	0.00	0.00
	Total	0.39	0.49
3	70 W	0.02	0.02
	150 W	0.04	0.05
	250 W	0.03	0.03
	400 W	0.16	0.20
	1000 W	0.16	0.21
	1500 W	0.00	0.00
	Total	0.40	0.50
4	70 W	0.08	0.09
	150 W	0.10	0.13
	250 W	0.12	0.14
	400 W	0.25	0.32
	1000 W	0.16	0.21
	1500 W	0.00	0.00
	Total	0.71	0.88
5	70 W	0.09	0.11
	150 W	0.11	0.14
	250 W	0.13	0.16
	400 W	0.33	0.42
	1000 W	0.16	0.21
	1500 W	0.00	0.00
	Total	0.83	1.03

Circular A–4 requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using nine rather than 30 years of fixture shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[66] DOE notes that the

[66] EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. While adding a 6-year review

review time frame established in EPCA generally does not overlap with the equipment lifetime, equipment manufacturing cycles or other factors specific to metal halide lamp fixtures. Thus, this information is presented for informational purposes only and is not indicative of any change in DOE's analytical methodology. The NES results based on a 9-year analytical period are presented in Table VII.37. The impacts are counted over the lifetime of fixtures purchased in 2017–2025.

TABLE VII.37—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2025

Trial standard level	Equipment class	National primary energy savings quads	
		Low-shipments scenario	High-shipments scenario
1	70 W	0.01	0.01
	150 W	0.01	0.01
	250 W	0.01	0.01
	400 W	0.05	0.05
	1000 W	0.08	0.08
	1500 W	0.00	0.00
	Total	0.15	0.16
2	70 W	0.01	0.01
	150 W	0.02	0.02
	250 W	0.01	0.01
	400 W	0.07	0.07
	1000 W	0.08	0.08
	1500 W	0.00	0.00
	Total	0.19	0.20
3	70 W	0.01	0.01
	150 W	0.02	0.02
	250 W	0.01	0.01
	400 W	0.07	0.07
	1000 W	0.08	0.08
	1500 W	0.00	0.00
	Total	0.19	0.20
4	70 W	0.04	0.05
	150 W	0.05	0.05
	250 W	0.06	0.06
	400 W	0.11	0.12
	1000 W	0.08	0.08
	1500 W	0.00	0.00
	Total	0.34	0.36
5	70 W	0.05	0.06
	150 W	0.05	0.06
	250 W	0.06	0.07
	400 W	0.15	0.16
	1000 W	0.08	0.08
	1500 W	0.00	0.00
	Total	0.39	0.42

b. Net Present Value of Customer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for customers that would result from the TSLs considered for metal halide lamp fixtures. In accordance with OMB's guidelines on regulatory analysis,[67] DOE calculated the NPV using both a 7-percent and a 3-percent real discount rate. The 7-percent rate is an estimate of the average before-tax rate of return on private capital in the U.S. economy, and reflects the returns on real estate and small business capital as well as corporate capital. This discount rate approximates the opportunity cost of capital in the private sector (OMB analysis has found the average rate of return on capital to be near this rate). The 3-percent rate reflects the potential effects of standards on private consumption (*e.g.*, through higher prices for products and reduced purchases of energy). This rate represents the rate at which society discounts future consumption flows to their present

to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6-year period and that the 3-year compliance date may yield to the 6-year backstop.

[67] OMB Circular A–4, section E (Sept. 17, 2003). Available at: *www.whitehouse.gov/omb/circulars_a004_a-4.*

value. It can be approximated by the real rate of return on long-term government debt (*i.e.*, yield on United States Treasury notes), which has averaged about 3 percent for the past 30 years.

Table VII.38 shows the customer NPV results for each TSL DOE considered for metal halide lamp fixtures, using both 7-percent and 3-percent discount rates. In each case, the impacts cover the lifetime of equipment purchased in 2017–2046. See chapter 11 of the final rule TSD for more detailed NPV results.

TABLE VII.38—NET PRESENT VALUE OF CUSTOMER BENEFITS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046

Trial standard level	Equipment class	Net present value billion 2012$			
		Low-shipments scenario		High-shipments scenario	
		7-percent discount rate	3-percent discount rate	7-percent discount rate	3-percent discount rate
1	70 W	0.018	0.033	0.019	0.035
	150 W	0.031	0.074	0.035	0.089
	250 W	0.007	0.045	0.009	0.053
	400 W	0.004	0.102	0.008	0.134
	1000 W	0.198	0.528	0.234	0.656
	1500 W	0.000	0.000	0.000	0.000
	Total	0.257	0.783	0.304	0.968
2	70 W	0.016	0.041	0.017	0.044
	150 W	0.046	0.119	0.054	0.144
	250 W	0.007	0.045	0.009	0.053
	400 W	0.022	0.183	0.030	0.236
	1000 W	0.198	0.528	0.234	0.656
	1500 W	0.000	0.000	0.000	0.000
	Total	0.289	0.915	0.343	1.134
3	70 W	0.016	0.041	0.017	0.044
	150 W	0.046	0.119	0.054	0.144
	250 W	−0.014	0.026	−0.015	0.033
	400 W	0.022	0.183	0.030	0.236
	1000 W	0.198	0.528	0.234	0.656
	1500 W	0.000	0.000	0.000	0.000
	Total	0.267	0.896	0.319	1.114
4	70 W	−0.091	−0.118	−0.102	−0.135
	150 W	0.074	0.218	0.087	0.269
	250 W	−0.352	−0.606	−0.401	−0.721
	400 W	−0.636	−1.057	−0.722	−1.244
	1000 W	0.198	0.528	0.234	0.656
	1500 W	−0.005	−0.007	−0.005	−0.008
	Total	−0.812	−1.042	−0.910	−1.183
5	70 W	−0.114	−0.146	−0.128	−0.166
	150 W	0.049	0.177	0.059	0.221
	250 W	−0.283	−0.460	−0.321	−0.543
	400 W	−0.741	−1.201	−0.839	−1.409
	1000 W	0.198	0.528	0.234	0.656
	1500 W	−0.007	−0.010	−0.008	−0.012
	Total	−0.898	−1.111	−1.004	−1.252

The NPV results based on the aforementioned 9-year analytical period are presented in Table VII.39. The impacts are counted over the lifetime of fixtures purchased in 2017–2025. As mentioned previously, this information is presented for informational purposes only and is not indicative of any change in DOE's analytical methodology or decision criteria.

TABLE VII.39—NET PRESENT VALUE OF CUSTOMER BENEFITS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2025

Trial standard level	Equipment class	Net present value billion 2012$			
		Low-shipments scenario		High-shipments scenario	
		7-percent discount rate	3-percent discount rate	7-percent discount rate	3-percent discount rate
1	70 W	0.018	0.033	0.019	0.035
	150 W	0.021	0.043	0.022	0.046
	250 W	0.003	0.025	0.004	0.026
	400 W	−0.004	0.038	−0.004	0.041
	1000 W	0.122	0.269	0.131	0.289
	1500 W	0.000	0.000	0.000	0.000
	Total	0.160	0.408	0.171	0.436
2	70 W	0.016	0.037	0.017	0.039
	150 W	0.030	0.065	0.032	0.070
	250 W	0.003	0.025	0.004	0.026
	400 W	0.005	0.074	0.005	0.079
	1000 W	0.122	0.269	0.131	0.289
	1500 W	0.000	0.000	0.000	0.000
	Total	0.177	0.470	0.189	0.502
3	70 W	0.016	0.037	0.017	0.039
	150 W	0.030	0.065	0.032	0.070
	250 W	−0.013	0.009	−0.013	0.010
	400 W	0.005	0.074	0.005	0.079
	1000 W	0.122	0.269	0.131	0.289
	1500 W	0.000	0.000	0.000	0.000
	Total	0.161	0.455	0.172	0.486
4	70 W	−0.064	−0.072	−0.068	−0.077
	150 W	0.046	0.112	0.049	0.120
	250 W	−0.241	−0.353	−0.253	−0.373
	400 W	−0.440	−0.635	−0.462	−0.669
	1000 W	0.122	0.269	0.131	0.289
	1500 W	−0.003	−0.004	−0.003	−0.004
	Total	−0.580	−0.683	−0.607	−0.714
5	70 W	−0.081	−0.092	−0.087	−0.099
	150 W	0.029	0.088	0.031	0.094
	250 W	−0.196	−0.274	−0.206	−0.289
	400 W	−0.514	−0.729	−0.540	−0.768
	1000 W	0.122	0.269	0.131	0.289
	1500 W	−0.005	−0.006	−0.005	−0.006
	Total	−0.645	−0.744	−0.676	−0.779

Finally, DOE evaluated the NPV results for both indoor and outdoor fixtures for each equipment class. Table VII.40 gives the NPV associated with each equipment class broken down into indoor and outdoor fixture environments.

TABLE VII.40—NET PRESENT VALUE OF CUSTOMER BENEFITS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046

[Low shipments, by fixture environment]

Trial standard level	Equipment class	Net present value billion 2012$			
		Indoor fixtures		Outdoor fixtures	
		7-percent discount rate	3-percent discount rate	7-percent discount rate	3-percent discount rate
1	70 W	0.001	0.001	0.017	0.033
	150 W	0.008	0.019	0.023	0.056

TABLE VII.40—NET PRESENT VALUE OF CUSTOMER BENEFITS FOR METAL HALIDE LAMP FIXTURE TRIAL STANDARD LEVELS FOR UNITS SOLD IN 2017–2046—Continued

[Low shipments, by fixture environment]

Trial standard level	Equipment class	Net present value billion 2012$			
		Indoor fixtures		Outdoor fixtures	
		7-percent discount rate	3-percent discount rate	7-percent discount rate	3-percent discount rate
	250 W	0.003	0.014	0.004	0.031
	400 W	0.002	0.028	0.001	0.075
	1000 W	0.054	0.136	0.143	0.393
	1500 W	0.000	0.000	0.000	0.000
	Total	0.068	0.197	0.189	0.586
2	70 W	0.000	0.001	0.016	0.040
	150 W	0.022	0.051	0.024	0.068
	250 W	0.003	0.014	0.004	0.031
	400 W	0.008	0.049	0.014	0.134
	1000 W	0.054	0.136	0.143	0.393
	1500 W	0.000	0.000	0.000	0.000
	Total	0.087	0.251	0.201	0.664
3	70 W	0.000	0.001	0.016	0.040
	150 W	0.022	0.051	0.024	0.068
	250 W	−0.002	0.010	−0.012	0.016
	400 W	0.008	0.049	0.014	0.134
	1000 W	0.054	0.136	0.143	0.393
	1500 W	0.000	0.000	0.000	0.000
	Total	0.082	0.247	0.185	0.650
4	70 W	0.001	0.002	−0.092	−0.119
	150 W	0.036	0.080	0.038	0.137
	250 W	−0.050	−0.082	−0.302	−0.524
	400 W	−0.121	−0.192	−0.515	−0.865
	1000 W	0.054	0.136	0.143	0.393
	1500 W	−0.001	−0.002	−0.003	−0.005
	Total	−0.081	−0.059	−0.731	−0.983
5	70 W	−0.004	−0.003	−0.110	−0.142
	150 W	0.029	0.069	0.020	0.108
	250 W	−0.030	−0.041	−0.253	−0.419
	400 W	−0.151	−0.234	−0.589	−0.967
	1000 W	0.054	0.136	0.143	0.393
	1500 W	−0.002	−0.002	−0.005	−0.007
	Total	−0.103	−0.075	−0.794	−1.035

c. Impacts on Employment

DOE estimated the indirect employment impacts of potential standards on the economy in general, assuming that energy conservation standards for metal halide lamp fixtures will reduce energy bills for fixture users and that the resulting net savings will be redirected to other forms of economic activity. DOE used an input/output model of the U.S. economy to estimate these effects, including the demand for labor as described in section V.J.

The input/output model results suggest that today's adopted standards are likely to increase the net labor demand. The gains, however, would most likely be small relative to total national employment, and neither the BLS data nor the input/output model DOE uses includes the quality or wage level of the jobs. As shown in Table VII.41, DOE estimates that net indirect employment impacts from adopted fixture standards are small relative to the national economy.

TABLE VII.41—NET CHANGE IN JOBS FROM INDIRECT EMPLOYMENT EFFECTS UNDER FIXTURE TSLS

Analysis period year	Trial standard level	Net national change in jobs	
		Low shipments scenario, roll-up	High shipments scenario, roll-up
2018	1	−60	150
	2	−85	260

TABLE VII.41—NET CHANGE IN JOBS FROM INDIRECT EMPLOYMENT EFFECTS UNDER FIXTURE TSLs—Continued

Analysis period year	Trial standard level	Net national change in jobs	
		Low shipments scenario, roll-up	High shipments scenario, roll-up
	3	−105	405
	4	−405	820
	5	−470	705
2022	1	135	650
	2	170	945
	3	155	1,300
	4	65	2,755
	5	80	2,655

4. Impact on Utility or Performance of Equipment

As presented in section V.B of this notice, DOE concluded that none of the TSLs that were analyzed would reduce the utility or performance of the MHLFs under consideration in this rulemaking. Furthermore, manufacturers currently offer ballasts that meet or exceed the adopted standards in all equipment classes. (42 U.S.C. 6295(o)(2)(B)(i)(IV))

5. Impact of Any Lessening of Competition

EPCA directs DOE to consider any lessening of competition that is likely to result from standards. It also directs the Attorney General of the United States (Attorney General) to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(i)(V) and (B)(ii)). To assist the Attorney General in making a determination for MHLF standards, DOE provided the Department of Justice (DOJ) with copies of the NOPR and the TSD for review. DOE received comments from DOJ stating the proposed energy conservation standards for MHLFs are unlikely to have a significant adverse impact on competition.

6. Need of the Nation To Conserve Energy

An improvement in the energy efficiency of the products subject to today's rule is likely to improve the security of the nation's energy system by reducing overall demand for energy. Reduced electricity demand may also improve the reliability of the electricity system. Reductions in national electric generating capacity estimated for each considered TSL are reported in chapter 14 of the final rule TSD.

Energy savings from new and amended energy conservation standards for fixtures could produce environmental benefits in the form of reduced emissions of air pollutants and GHGs associated with electricity production. Table VII.42 and Table VII.43 provide DOE's estimate of cumulative emissions reductions projected to result from the TSLs considered in this rulemaking, for the low and high shipment scenarios, respectively. The tables include both power sector emissions and upstream emissions. The upstream emissions were calculated using the multipliers discussed in section V.L. DOE reports annual emissions reductions for each TSL in the emissions analysis in chapter 16 the final rule TSD.

TABLE VII.42—CUMULATIVE EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES

[Low shipments scenario]

	Trial standard level				
	1	2	3	4	5
Power Sector Emissions					
CO_2 (million metric tons)	16.80	21.24	21.80	38.30	44.93
NO_X (thousand tons)	8.85	11.18	11.48	20.16	23.64
Hg (tons)	0.04	0.05	0.05	0.08	0.10
N_2O (thousand tons)	0.36	0.45	0.46	0.81	0.95
CH_4 (thousand tons)	2.04	2.59	2.65	4.66	5.47
SO_2 (thousand tons)	29.48	37.29	38.26	67.25	78.95
Upstream Emissions					
CO_2 (million metric tons)	0.98	1.24	1.27	2.23	2.62
NO_X (thousand tons)	13.45	17.01	17.45	30.68	36.00
Hg (tons)	0.001	0.001	0.001	0.001	0.001
N_2O (thousand tons)	0.01	0.01	0.01	0.02	0.03
CH_4 (thousand tons)	81.69	103.31	106.01	186.34	218.69
SO_2 (thousand tons)	0.21	0.27	0.27	0.48	0.56
Total Emissions					
CO_2 (million metric tons)	17.78	22.48	23.07	40.53	47.54
NO_X (thousand tons)	22.29	28.19	28.93	50.84	59.64
Hg (tons)	0.04	0.05	0.05	0.08	0.10
N_2O (thousand tons)	0.37	0.46	0.47	0.83	0.98

TABLE VII.42—CUMULATIVE EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES—Continued

[Low shipments scenario]

	Trial standard level				
	1	2	3	4	5
CH_4 (thousand tons)	83.74	105.90	108.66	191.01	224.16
SO_2 (thousand tons)	29.69	37.55	38.53	67.73	79.51

TABLE VII.43—CUMULATIVE EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES

[High shipments scenario]

	Trial standard level				
	1	2	3	4	5
Power Sector Emissions					
CO_2 (*million metric tons*)	20.78	26.26	26.95	47.13	55.37
NO_X (*thousand tons*)	10.89	13.76	14.12	24.69	29.00
Hg (*tons*)	0.05	0.06	0.06	0.10	0.12
N_2O (*thousand tons*)	0.46	0.58	0.60	1.04	1.23
CH_4 (*thousand tons*)	2.57	3.25	3.33	5.83	6.85
SO_2 (*thousand tons*)	37.14	46.92	48.15	84.20	99.02
Upstream Emissions					
CO_2 (*million metric tons*)	1.22	1.54	1.59	2.77	3.26
NO_X (*thousand tons*)	16.83	21.26	21.81	38.16	44.85
Hg (*tons*)	0.001	0.001	0.001	0.001	0.002
N_2O (*thousand tons*)	0.01	0.02	0.02	0.03	0.03
CH_4 (*thousand tons*)	102.23	129.15	132.54	231.83	272.53
SO_2 (*thousand tons*)	0.26	0.33	0.34	0.59	0.70
Total Emissions					
CO_2 (*million metric tons*)	22.01	27.80	28.53	49.90	58.63
NO_X (*thousand tons*)	27.72	35.02	35.93	62.85	73.86
Hg (*tons*)	0.05	0.06	0.06	0.10	0.12
N_2O (*thousand tons*)	0.47	0.60	0.61	1.07	1.26
CH_4 (*thousand tons*)	104.80	132.40	135.87	237.66	279.39
SO_2 (*thousand tons*)	37.40	47.25	48.49	84.80	99.72

As discussed in section V.L, DOE did not report SO_2 emissions reductions from power plants because there is uncertainty about the effect of energy conservation standards on the overall level of SO_2 emissions in the United States due to new emissions standards for power plants under the MATS rule. DOE also did not include NO_X emissions reductions from power plants in states subject to CAIR because an energy conservation standard would not affect the overall level of NO_X emissions in those states due to the emissions caps.

As part the analysis for this final rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 and NO_X that DOE estimated for each of the TSLs considered. As discussed in section V.M.1, DOE used values for the SCC developed by an interagency process. The interagency group selected four sets of SCC values for use in regulatory analyses. Three sets are based on the average SCC from three integrated assessment models, at discount rates of 2.5 percent, 3 percent, and 5 percent. The fourth set, which represents the 95th-percentile SCC estimate across all three models at a 3-percent discount rate, is included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The four SCC values for CO_2 emissions reductions in 2015, expressed in 2012$, are $11.8/ton, $39.7/ton, $61.2/ton, and $117.0/ton. These values for later years are higher due to increasing emissions-related costs as the magnitude of projected climate change increases.

Table VII.44 and Table VII.45 present the global value of CO_2 emissions reductions at each TSL for the low and high shipment scenarios, respectively. DOE calculated domestic values as a range from 7 percent to 23 percent of the global values, and these results are presented in chapter 17 of the final rule TSD.

TABLE VII.44—GLOBAL PRESENT VALUE OF CO_2 EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES

[Low shipments scenario]

TSL	SCC scenario*			
	5% discount rate, average	3% discount rate, average	2.5% discount rate, average	3% discount rate, 95th percentile
	million 2012$			
Power Sector Emissions				
1	109.3	509.9	813.4	1,574.7
2	138.2	644.8	1,028.7	1,991.6
3	141.8	661.8	1,055.7	2,043.9
4	249.2	1,162.7	1,854.8	3,591.3
5	291.9	1,362.9	2,174.5	4,209.8
Upstream Emissions				
1	6.2	29.3	46.8	90.6
2	7.9	37.1	59.2	114.6
3	8.1	38.0	60.8	117.6
4	14.2	66.9	106.9	206.8
5	16.6	78.4	125.3	242.5
Total Emissions				
1	115	539.2	860.2	1,665.3
2	146	681.9	1,087.9	2,106.2
3	150	699.8	1,116.5	2,161.5
4	263	1,229.6	1,961.7	3,798.1
5	309	1,441.3	2,299.8	4,452.3

*For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2 and $117.0 per metric ton (2012$).

TABLE VII.45—GLOBAL PRESENT VALUE OF CO_2 EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES

[High shipments scenario]

TSL	SCC scenario*			
	5% discount rate, average	3% discount rate, average	2.5% discount rate, average	3% discount rate, 95th percentile
	million 2012$			
Power Sector Emissions				
1	130.4	617.9	988.6	1,909.5
2	164.8	780.8	1,249.3	2,413.0
3	169.1	801.4	1,282.2	2,476.6
4	296.0	1,402.5	2,243.7	4,334.3
5	347.3	1,646.3	2,634.1	5,088.0
Upstream Emissions				
1	7.5	35.9	57.6	111.1
2	9.5	45.4	72.7	140.4
3	9.7	46.6	74.7	144.1
4	17.0	81.5	130.7	252.2
5	20.0	95.7	153.5	296.2
Total Emissions				
1	137.9	653.8	1,046.2	2,020.6
2	174.2	826.2	1,322.0	2,553.4
3	178.8	848.0	1,356.8	2,620.7
4	313.1	1,484.0	2,374.3	4,586.5
5	367.2	1,742.1	2,787.6	5,384.2

*For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2 and $117.0 per metric ton (2012$).

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the world economy continues to evolve rapidly. Thus, any value placed in this rulemaking on reducing CO_2 emissions is subject to change. DOE, together with other Federal agencies, will continue to review various methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. However, consistent with DOE's legal obligations, and taking into account the uncertainty involved with this particular issue, DOE has included in this NOPR the most recent values and analyses resulting from the ongoing interagency review process.

DOE also estimated a range for the cumulative monetary value of the economic benefits associated with NO_X and Hg emissions reductions anticipated to result from amended metal halide lamp fixture standards. Estimated monetary benefits for CO_2 and NO_X emission reductions are detailed in chapter 17 of the final rule TSD.

The NPV of the monetized benefits associated with emissions reductions can be viewed as a complement to the NPV of the customer savings calculated for each TSL considered in this rulemaking. The dollar-per-ton values that DOE used are discussed in section V.M. Table VII.46 presents the present value of cumulative NO_X emissions reductions for each TSL calculated using the average dollar-per-ton values and 7-percent and 3-percent discount rates.

TABLE VII.46—PRESENT VALUE OF NO_X EMISSIONS REDUCTION FOR POTENTIAL STANDARDS FOR METAL HALIDE LAMP FIXTURES

TSL	Low shipments scenario		High shipments scenario	
	3% discount rate	7% discount rate	3% discount rate	7% discount rate
	million 2012$			
Power Sector Emissions				
1	12.0	5.8	14.1	6.6
2	15.2	7.4	17.9	8.3
3	15.6	7.6	18.3	8.5
4	27.4	13.3	32.1	14.9
5	32.0	15.5	37.6	17.5
Upstream Emissions				
1	17.4	7.9	20.8	9.1
2	22.0	10.0	26.3	11.4
3	22.6	10.2	27.0	11.7
4	39.7	18.0	47.3	20.6
5	46.5	21.0	55.5	24.1
Total Emissions				
1	29.4	13.7	35.0	15.6
2	37.2	17.3	44.2	19.8
3	38.2	17.8	45.4	20.3
4	67.0	31.2	79.4	35.5
5	78.5	36.5	93.1	41.6

The NPV of the monetized benefits associated with emissions reductions can be viewed as a complement to the NPV of the customer savings calculated for each TSL considered in this rulemaking. Table VII.47 and Table VII.48 present the NPV values that result from adding the estimates of the potential economic benefits resulting from reduced CO_2 and NO_X emissions in each of four valuation scenarios to the NPV of customer savings calculated for each TSL considered in this rulemaking, at both a 7-percent and a 3-percent discount rate, and for the low and high shipment scenarios, respectively. The CO_2 values used in the columns of each table correspond to the four scenarios for the valuation of CO_2 emission reductions discussed above.

TABLE VII.47—METAL HALIDE LAMP FIXTURE TSLS: NET PRESENT VALUE OF CUSTOMER SAVINGS COMBINED WITH NET PRESENT VALUE OF MONETIZED BENEFITS FROM CO_2 AND NO_X EMISSIONS REDUCTIONS

[Low shipments scenario]

TSL	Customer NPV at 3% discount rate added with:			
	SCC value of $11.8/metric ton CO_2* and medium value for NO_X**	SCC value of $39.7/metric ton CO_2* and medium value for NO_X**	SCC value of $61.2/metric ton CO_2* and medium value for NO_X**	SCC value of $117.0/metric ton CO_2* and medium value for NO_X**
	billion 2012$			
1	0.928	1.352	1.673	2.478
2	1.099	1.634	2.040	3.059
3	1.084	1.634	2.051	3.096
4	−0.712	0.255	0.987	2.823
5	−0.724	0.409	1.268	3.420
	Customer NPV at 7% discount rate added with:			
	billion 2012$			
1	0.386	0.810	1.131	1.936
2	0.452	0.988	1.394	2.412
3	0.435	0.985	1.402	2.447
4	−0.518	0.449	1.181	3.017
5	−0.553	0.580	1.439	3.591

*These label values represent the global SCC in 2015, in 2012$. The present values have been calculated with scenario-consistent discount rates.

**Medium Value corresponds to $2,639 per ton of NO_X emissions.

TABLE VII.48—METAL HALIDE LAMP FIXTURE TSLS: NET PRESENT VALUE OF CUSTOMER SAVINGS COMBINED WITH NET PRESENT VALUE OF MONETIZED BENEFITS FROM CO_2 AND NO_X EMISSIONS REDUCTIONS

[High Shipments Scenario]

TSL	Customer NPV at 3% discount rate added with:			
	SCC value of $11.8/metric ton CO_2* and medium value for NO_X**	SCC value of $39.7/metric ton CO_2* and medium value for NO_X**	SCC value of $61.2/metric ton CO_2* and medium value for NO_X**	SCC value of $117.0/metric ton CO_2* and medium value for NO_X**
	billion 2012$			
1	1.141	1.657	2.049	3.024
2	1.353	2.005	2.501	3.732
3	1.338	2.008	2.516	3.780
4	−0.790	0.380	1.271	3.483
5	−0.792	0.583	1.628	4.225
	Customer NPV at 7% discount rate added with:			
	billion 2012$			
1	0.458	0.974	1.366	2.340
2	0.537	1.189	1.685	2.916
3	0.518	1.188	1.696	2.960
4	−0.561	0.610	1.500	3.712
5	−0.595	0.780	1.825	4.422

*These label values represent the global SCC in 2015, in 2012$. The present values have been calculated with scenario-consistent discount rates.

**Medium Value corresponds to $2,639 per ton of NO_X emissions.

Although adding the value of customer savings to the values of emission reductions provides a valuable perspective, the following should be considered: (1) The national customer savings are domestic U.S. customer monetary savings found in market transactions, while the values of emissions reductions are based on estimates of marginal social costs, which, in the case of CO_2, are based on a global value; and (2) the assessments of customer savings and emissions-related benefits are performed with different computer models, leading to different time frames for analysis. For fixtures, the present value of national customer savings is measured for the period in which units shipped in 2017–2046 continue to operate. The SCC values, on the other hand, reflect the

present value of future climate-related impacts resulting from the emission of one metric ton of CO_2 in each year. These impacts continue well beyond 2100.

C. Conclusions

DOE is subject to the EPCA requirement that any new or amended energy conservation standard for any type (or class) of covered equipment be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens to the greatest extent practicable, in light of the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

DOE considered the impacts of MHLF standards at each trial standard level, beginning with the max-tech level, to determine whether that level met the evaluation criteria. If the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

DOE discusses the benefits and/or burdens of each trial standard level in the following sections based on the quantitative analytical results for each trial standard level (presented in section VII.A) such as national energy savings, net present value (discounted at 7 and 3 percent), emissions reductions, industry net present value, life-cycle cost, and customers' installed price increases. Beyond the quantitative results, DOE also considers other burdens and benefits that affect economic justification, including how technological feasibility, manufacturer costs, and impacts on competition may affect the economic results presented.

To aid the reader as DOE discusses the benefits and burdens of each trial standard level, DOE has included the following tables (Table VII.49 and Table VII.50) that summarize DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. Section VII.B.1 presents the estimated impacts of each TSL for the LCC subgroup analysis.

TABLE VII.49—SUMMARY OF RESULTS FOR METAL HALIDE LAMP FIXTURES

[Low shipments scenario]

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
National Energy Savings (quads).	0.31	0.39	0.40	0.71	0.83
NPV of Customer Benefits (2012$ billion)					
3% discount rate	0.78	0.92	0.90	(1.04)	(1.11)
7% discount rate	0.26	0.29	0.27	(0.81)	(0.90)
Industry Impacts*					
Ballast + Fixture Industry NPV (2012$million)					
(Base Case Industry NPV of $413 million).	393	391	390	336	305
Ballast + Fixture Industry NPV (change in 2012$million).	(20.1)	(21.5)	(22.6)	(76.6)	(107.5)
Ballast + Fixture Industry NPV (% change).	−4.9%	−5.2%	−5.5%	−18.6%	−26.1%
Cumulative Emissions Reduction					
CO_2 (Mt)	17.78	22.48	23.07	40.53	47.54
SO_2 (kt)	29.69	37.55	38.53	67.73	79.51
NO_X (kt)	22.29	28.19	28.93	50.84	59.64
Hg (t)	0.04	0.05	0.05	0.08	0.10
CH_4 (kt)	83.74	105.90	108.66	191.01	224.16
N_2O (kt)	0.37	0.46	0.47	0.83	0.98
Value of Cumulative Emissions Reduction					
CO_2 (2012$ billion)**	0.1 to 1.7	0.1 to 2.1	0.1 to 2.2	0.3 to 3.8	0.3 to 4.5
NO_X—3% discount rate (2012$ million)**.	29.4	37.2	38.2	67.0	78.5
NO_X—7% discount rate (2012$ million)**.	13.7	17.3	17.8	31.2	36.5
Mean LCC Savings (and Percent Customers Experiencing Net Benefit)*** (2012$)					
50to100W_Ind_OtherV****† (magnetic baseline).	26.97 (100)	27.00 (100)	27.00 (100)	42.50 (82)	37.25 (79)
50to100W_Outd_OtherV (magnetic baseline).	34.24 (98)	34.88 (97)	34.88 (97)	−4.98 (51)	−11.15 (49)
50to100W_Ind_OtherV (electronic baseline).	—	—	—	—	−5.25 (10)

TABLE VII.49—SUMMARY OF RESULTS FOR METAL HALIDE LAMP FIXTURES—Continued

[Low shipments scenario]

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
50to100W_Outd_OtherV (electronic baseline).	—	—	—	—	−6.17 (12)
101to150W_Ind_OtherV‡	22.43 (100)	24.63 (99)	24.63 (99)	89.67 (94)	76.11 (89)
101to150W_Outd_OtherV	27.37 (97)	30.70 (97)	30.70 (97)	52.23 (66)	36.60 (62)
151to250W_Ind_OtherV‡	4.51 (60)	4.51 (60)	−1.07 (37)	−59.67 (18)	−40.33 (29)
151to250W_Outd_OtherV	6.74 (67)	6.74 (67)	1.48 (45)	−119.65 (24)	−97.86 (29)
251to500W_Ind_OtherV	2.83 (47)	7.95 (54)	7.95 (54)	−107.74 (8)	130.60 (6)
251to500W_Outd_OtherV	6.16 (55)	13.15 (62)	13.15 (62)	−165.30 (19)	−187.69 (16)
501to1000W_Ind_OtherV	1221.54 (100)	1221.54 (100)	1221.54 (100)	1221.54 (100)	1221.54 (100)
501to1000W_Outd_OtherV.	1631.94 (98)	1631.94 (98)	1631.94 (98)	1631.94 (98)	1631.94 (98)
1001to2000W_Ind_OtherV.	—	—	—	−67.15 (0)	−93.06 (0)
1001to2000W_Outd_OtherV.	—	—	—	−63.71 (0)	−88.03 (0)
Median PBP (years)					
50to100W_Ind_OtherV (magnetic baseline).	1.4	4.5	4.5	3.7	6.0
50to100W_Outd_OtherV (magnetic baseline).	1.4	4.5	4.5	12.0	14.7
50to100W_Ind_OtherV (electronic baseline).	—	—	—	—	31.5
50to100W_Outd_OtherV (electronic baseline).	—	—	—	—	55.8
101to150W_Ind_OtherV‡	4.3	7.3	7.3	2.5	4.8
101to150W_Outd_OtherV	4.5	8.1	8.1	7.5	10.3
151to250W_Ind_OtherV‡	14.2	14.2	17.9	113.2	38.4
151to250W_Outd_OtherV	17.4	17.4	22.8	326.7	135.1
251to500W_Ind_OtherV	16.2	15.0	15.0	369.2	137.2
251to500W_Outd_OtherV	19.9	18.4	18.4	Never	Never
501to1000W_Ind_OtherV	0.8	0.8	0.8	0.8	0.8
501to1000W_Outd_OtherV.	0.8	0.8	0.8	0.8	0.8
1001to2000W_Ind_OtherV.	—	—	—	209.4	162.7
1001to2000W_Outd_OtherV.	—	—	—	244.5	190.0
Employment Impacts					
Direct Employment Impacts.	47—(339)	62—(339)	69—(339)	73—(339)	93—(339)
Indirect Domestic Jobs √√.	135	170	155	65	80

* INPV results are shown under the preservation of operating profit markup scenario.

** Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions. Economic value of NO_X reductions is based on estimates at $2639/ton.

*** For LCCs, a negative value means an increase in LCC by the amount indicated.

**** "Indoor" and "outdoor" as defined in section V.A.2.

† Equipment class abbreviations in the form of 50 to100W_Ind_OtherV refers to the equipment class of fixtures with (1) a rated lamp wattage of 50 W to 100 W, (2) an indoor operating location, and (3) a tested input voltage other than 480 V. See section V.A.2 for more detail on equipment class distinctions.

‡ The >100 W and ≤150 W equipment classes include 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 watt lamps that are also rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A) and contain a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007. The ≥150 W and ≤250 W equipment classes contain all other covered fixtures that are rated only for 150 watt lamps.

√√ Changes in 2022.

TABLE VII.50—SUMMARY OF RESULTS FOR METAL HALIDE LAMP FIXTURES

[High shipments scenario)

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
National Energy Savings (quads)	0.39	0.49	0.50	0.88	1.03
NPV of Customer Benefits (2012$ billion)					
3% discount rate	0.97	1.13	1.11	(1.18)	(1.25)
7% discount rate	0.30	0.34	0.32	(0.91)	(1.00)
Industry Impacts *					
Ballast + Fixture Industry NPV (2012$million) (Base Case Industry NPV of $453 million)	478	491	497	501	497
Ballast + Fixture Industry NPV (change in 2012$million)	25.3	38.0	44.0	48.1	44.2
Ballast + Fixture Industry NPV (% change)	5.6%	8.4%	9.7%	10.6%	9.7%
Cumulative Emissions Reduction					

TABLE VII.50—SUMMARY OF RESULTS FOR METAL HALIDE LAMP FIXTURES—Continued

[High shipments scenario)

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
CO_2 (Mt)	22.01	27.80	28.53	49.90	58.63
SO_2 (kt)	37.40	47.25	48.49	84.80	99.72
NO_X (kt)	27.72	35.02	35.93	62.85	73.86
Hg (t)	0.05	0.06	0.06	0.10	0.12
CH_4 (kt)	104.80	132.40	135.87	237.66	279.39
N_2O (kt)	0.47	0.60	0.61	1.07	1.26
Value of Cumulative Emissions Reduction					
CO_2 (2012$ billion)**	0.1 to 2.0	0.2 to 2.6	0.2 to 2.6	0.3 to 4.6	0.4 to 5.4
NO_X—3% discount rate (2012$ million)**	35.0	44.2	45.4	79.4	93.1
NO_X—7% discount rate (2012$ million)**	15.6	19.8	20.3	35.5	41.6
Mean LCC Savings (and Percent Customers Experiencing Net Benefit)*** (2012$)					
50to100W_Ind_OtherV****† (magnetic baseline)	26.97 (100)	27.00 (100)	27.00 (100)	42.50 (82)	37.25 (79)
50to100W_Outd_OtherV (magnetic baseline)	34.24 (98)	34.88 (97)	34.88 (97)	−4.98 (51)	−11.15 (49)
50to100W_Ind_OtherV (electronic baseline)					−5.25 (10)
50to100W_Outd_OtherV (electronic baseline)					−6.17 (12)
100to149W_Ind_OtherV‡	22.43 (100)	24.63 (99)	24.63 (99)	89.67 (94)	76.11 (89)
100to149W_Outd_OtherV	27.37 (97)	30.70 (97)	30.70 (97)	52.23 (66)	36.60 (62)
150to250W_Ind_OtherV‡	4.51 (60)	4.51 (60)	−1.07 (37)	−59.67 (18)	−40.33 (29)
150to250W_Outd_OtherV	6.74 (67)	6.74 (67)	1.48 (45)	−119.65 (24)	−97.86 (29)
251to500W_Ind_OtherV	2.83 (47)	7.95 (54)	7.95 (54)	−107.74 (8)	130.60 (6)
251to500W_Outd_OtherV	6.16 (55)	13.15 (62)	13.15 (62)	−165.30 (19)	−187.69 (16)
501to1000W_Ind_OtherV	1221.54 (100)	1221.54 (100)	1221.54 (100)	1221.54 (100)	1221.54 (100)
501to1000W_Outd_OtherV	1631.94 (98)	1631.94 (98)	1631.94 (98)	1631.94 (98)	1631.94 (98)
1001to2000W_Ind_OtherV				−67.15 (0)	−93.06 (0)
1001to2000W_Outd_OtherV				−63.71 (0)	−88.03 (0)
Median PBP (years)					
50to100W_Ind_OtherV (magnetic baseline)	1.4	4.5	4.5	3.7	6.0
50to100W_Outd_OtherV (magnetic baseline)	1.4	4.5	4.5	12.0	14.7
50to100W_Ind_OtherV (electronic baseline)					31.5
50to100W_Outd_OtherV (electronic baseline)					55.8
100to149W_Ind_OtherV‡	4.3	7.3	7.3	2.5	4.8
100to149W_Outd_OtherV	4.5	8.1	8.1	7.5	10.3
150to25W0_Ind_OtherV‡	14.2	14.2	17.9	113.2	38.4
150to250W_Outd_OtherV	17.4	17.4	22.8	326.7	135.1
251to500W_Ind_OtherV	16.2	15.0	15.0	369.2	137.2
251to500W_Outd_OtherV	19.9	18.4	18.4	Never	Never
501to1000W_Ind_OtherV	0.8	0.8	0.8	0.8	0.8
501to1000W_Outd_OtherV	0.8	0.8	0.8	0.8	0.8
1001to2000W_Ind_OtherV				209.4	162.7
1001to2000W_Outd_OtherV				244.5	190.0
Employment Impacts					
Direct Employment Impacts	48–(345)	63–(345)	70–(345)	74–(345)	95–(345)
Indirect Domestic Jobs √√	650	945	1300	2755	2655

*INPV results are shown under the –flat markup scenario.

**Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions. Economic value of NO_X reductions is based on estimates at $2,639/ton.

***For LCCs, a negative value means an increase in LCC by the amount indicated.

****"Indoor" and "outdoor" as defined in section V.A.2.

†Equipment class abbreviations in the form of 50 to100W_Ind_OtherV refers to the equipment class of fixtures with (1) a rated lamp wattage of 50 W to 100 W, (2) an indoor operating location, and (3) a tested input voltage other than 480 V. See section V.A.2 for more detail on equipment class distinctions.

‡The >100 W and ≤150 W equipment classes include 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 watt lamps that are also rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A) and contain a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007. The ≥150 W and ≤250 W equipment classes contain all other covered fixtures that are rated only for 150 watt lamps.

√√Changes in 2022.

1. Trial Standard Level 5

DOE first considered the most efficient level, TSL 5, which would save an estimated total of 0.83 to 1.03 quads of energy for fixtures shipped in 2017 through 2046, a significant amount of energy. For the nation as a whole, TSL 5 would have net costs ranging from a decrease of $0.90 billion to a decrease of $1.0 billion at a 7-percent discount rate, and a decrease of $1.1 billion to a decrease of $1.3 billion at a 3-percent discount rate. The emissions reductions at TSL 5 are estimated to be 48 to 59 million metric tons (Mt) of CO_2, 80 to 100 kt of SO_2, 60 to 74 kt of NO_X, and 0.10 to 0.12 tons of Hg. As seen in section VII.B.1, customers have available designs that result in positive mean LCC savings for a majority of customers for only five out of twelve of the representative equipment classes, ranging from $37 to $1632, at TSL 5. The equipment classes with positive mean LCC savings for a majority of customers at TSL 5 are indoor fixtures at 70 W (compared to the magnetic 70 W baseline), 150 W, and 1000 W; and outdoor fixtures at 150 W and 1000 W. Additionally, DOE's NPV analysis

indicates (see Table VII.49) that most equipment classes experience a negative NPV at TSL 5. The equipment classes that have negative NPV at TSL 5 are indoor and outdoor 70 W, 250 W, 400 W, and 1500 W fixtures. The equipment classes with positive NPV at TSL 5 are indoor and outdoor 150 W and 1000 W fixtures. The projected change in industry value for MH ballast manufacturers would range from an increase of $15.0 million to a decrease of $19.0 million, or a net gain of 20.3 percent to a net loss of 28.3 percent in INPV. The projected change in industry value for MHLF manufacturers would range from an increase of $29.1 million to a decrease of $88.6 million, or a net gain of 7.7 percent to a net loss of 25.6 percent in INPV.

DOE based TSL 5 on the most efficient commercially available equipment for each representative equipment class analyzed. This TSL corresponds to a commercially available low-frequency electronic ballast for indoor and outdoor 70 W, 150 W, 250 W, 400 W fixtures, and a modeled magnetic ballast in 1000 W and 1500 W. TSL 5 also prohibits the use of probe-start ballasts in new 1000 W fixtures.

Although TSL 5 for 150 W MHLFs shows positive LCC savings and NPVs, DOE believes uncertainty remains regarding the cost effectiveness of electronic ballasts for these customers, especially in outdoor applications. There has been virtually no market penetration of electronic ballasts in outdoor applications according to DOE's shipment analysis. Further, DOE received comments from manufacturers and utilities that electronic ballasts are not suitable for outdoor applications due to their lower operating temperature limits, different sizes compared to magnetic ballasts, and susceptibility to transient voltage fluctuations. DOE has conducted significant research to address each one of these issues (see section V.C.8.b), but remains concerned that requiring electronic ballasts for 150 W MHLFs could cause disproportionate financial hardship for these customers. Therefore, DOE is not adopting an efficiency level that requires electronic ballasts in this final rule. DOE will continue to monitor the market share of electronic ballasts, particularly in outdoor applications, and may revisit this decision in future rulemakings.

After considering the analysis, the comments that DOE received on the NOPR, and the benefits and burdens of TSL 5, the Secretary has reached the following conclusion: The benefits of energy savings, emissions reductions (both in physical reductions and the monetized value of those reductions), and positive net economic savings to the nation for some equipment classes are outweighed by the negative NPV experienced in some equipment classes at both a 3-percent and 7-percent discount rate, the negative mean LCC savings experienced in most equipment classes, the negative mean LCC savings experienced by some customer subgroups, the potential decrease in INPV for manufacturers, and the uncertainty regarding electronic ballasts. Consequently, the Secretary has concluded that TSL 5 is not economically justified.

2. Trial Standard Level 4

DOE then considered TSL 4, which would save an estimated total of 0.71 to 0.88 quads of energy for fixtures shipped in 2017 through 2046, a significant amount of energy. For the nation as a whole, TSL 4 would have net costs ranging from a decrease of $0.81 billion to a decrease of $0.91 billion at a 7-percent discount rate, and a decrease of $1.0 billion to a decrease of $1.2 billion at a 3-percent discount rate. The emissions reduction at TSL 4 are estimated to be 41 to 50 Mt of CO_2, 68 to 85 kt of SO_2, 51 to 63 kt of NO_X, and 0.08 to 0.10 tons of Hg. As seen in section VII.B.1, for less than half of the representative equipment classes, customers have available designs that result in positive mean LCC savings for a majority of customers, ranging from $43 to $1632, at TSL 4. Additionally, DOE's NPV analysis indicates (see Table VI.34) that less than half of the representative classes have a positive NPV at TSL 4. The projected change in industry value for MH ballast manufacturers would range from an increase of $9.6 million to a decrease of $16.2 million, or a net gain of 12.9 percent to a net loss of 24.1 percent in INPV. The projected change in industry value for MHLF manufacturers would range from an increase of $38.6 million to a decrease of $60.4 million, or a net gain of 10.2 percent to a net loss of 17.5 percent in INPV.

TSL 4 represents the next highest EL for all equipment classes not justified at TSL 5. This TSL corresponds to a commercially available low-frequency electronic ballast in indoor and outdoor 70 W, 150 W, 250 W, and 400 W fixtures; a commercially available magnetic ballast in indoor and outdoor 1500 W fixtures; and a modeled magnetic ballast in indoor and outdoor 1000 W fixtures. TSL 4 also prohibits the use of probe-start ballasts in new 1000 W fixtures.

Although TSL 4 for 150 W MHLFs shows positive LCC savings and NPVs, DOE believes uncertainty remains regarding the cost effectiveness of electronic ballasts for these customers, especially in outdoor applications. There has been virtually no market penetration of electronic ballasts in outdoor applications according to DOE's shipment analysis. Further, DOE received comments from manufacturers and utilities that electronic ballasts are not suitable for outdoor applications due to their lower operating temperature limits, different sizes compared to magnetic ballasts, and susceptibility to transient voltage fluctuations. DOE has conducted significant research to address each one of these issues (see section V.C.8.b), but remains concerned that requiring electronic ballasts for 150 W MHLFs could cause disproportionate financial hardship for these customers. Therefore, DOE is not adopting an efficiency level that requires electronic ballasts in this final rule. DOE will continue to monitor the market share of electronic ballasts, particularly in outdoor applications, and may revisit this decision in future rulemakings.

After considering the analysis, the comments that DOE received on the NOPR, and the benefits and burdens of TSL 4, the Secretary has reached the following conclusion: At TSL 4, the benefits of energy savings, emissions reductions (both in physical reductions and the monetized value of those reductions), and positive net economic savings to the nation are outweighed by negative NPV experienced in some equipment classes at both 3-percent and 7-percent discount rate, the negative mean LCC savings experienced in some equipment classes, the negative mean LCC savings for the utility customer subgroup, the potential decrease in INPV for manufacturers, and the uncertainty regarding electronic ballasts. Consequently, the Secretary has concluded that TSL 4 is not economically justified.

3. Trial Standard Level 3

DOE then considered TSL 3, which would save an estimated total of 0.40 to 0.50 quads of energy for fixtures shipped in 2017 through 2046, a significant amount of energy. For the nation as a whole, TSL 3 would have positive net savings of $0.27 billion to $0.32 billion at a 7-percent discount rate and $0.90 billion to $1.1 billion at a 3-percent discount rate. The emissions reductions at TSL 3 are estimated to be 23 to 29 Mt of CO_2, 39 to 48 kt of SO_2, 29 to 36 kt of NO_X, and 0.05 to 0.06 tons of Hg. As seen in section VII.B.1, for most representative equipment classes, customers have available designs that result in positive mean LCC savings, ranging from $8 to $1632, at TSL 3.

DOE's NPV analysis indicates (see Table VI.34) that most equipment classes have a positive NPV at TSL 3, though indoor and outdoor 250 W customers experience negative NPV. The projected change in industry value for MH ballast manufacturers would range from an increase of $0.6 million to a decrease of $19.0 million, or a net gain of 0.8 percent to a net loss of 28.3 percent in INPV. The projected change in industry value for MHLF manufacturers would range from an increase of $43.4 million to a decrease of $3.6 million, or a net gain of 11.4 percent to a net loss of 1.1 percent in INPV.

TSL 3 represents the next highest EL for all equipment classes not justified at TSL 4, requiring that indoor and outdoor fixtures are set at the same ELs. This TSL corresponds to a modeled magnetic ballast in indoor and outdoor fixtures at 70 W, 150 W, 250 W, 400 W, and 1000 W. Indoor and outdoor fixtures at 1500 W would remain at baseline, with no new standards established. TSL 3 also prohibits the use of probe-start ballasts in new 1000 W fixtures.

After considering the analysis, the comments that DOE received on the preliminary analysis, and the benefits and burdens of TSL 3, the Secretary has reached the following conclusion: At TSL 3, the benefits of energy savings, emissions reductions (both in physical reductions and monetized value of those reductions), and positive net economic savings to the nation would be outweighed by the negative NPV experienced in the 250 W indoor and outdoor equipment classes at 7-percent discount rate and the potential decrease in INPV for manufacturers. Consequently, the Secretary has tentatively concluded that TSL 3 is not economically justified.

4. Trial Standard Level 2

DOE then considered TSL 2, which would save an estimated total of 0.39 to 0.49 quads of energy for fixtures shipped in 2017 through 2046, a significant amount of energy. For the nation as a whole, TSL 2 would have a positive net savings of $0.29 billion to $0.34 billion at a 7-percent discount rate, and $0.92 billion to $1.1 billion at a 3-percent discount rate. The emissions reductions at TSL 3 are estimated to be 23 to 28 Mt of CO_2, approximately 38 to 47 kt of SO_2, 28 to 35 kt of NO_X, and 0.05 to 0.06 tons of Hg. As seen in section VII.B.1, for all representative equipment classes, customers have available designs that result in positive mean LCC savings, ranging from $5 to $1,632, at TSL 2. DOE's NPV analysis indicates (see Table VI.34) that each equipment class has a positive NPV at TSL 2. The projected change in industry value for MH ballast manufacturers would range from a decrease of $0.4 million to a decrease of $17.9 million, or a net loss from 0.5 percent to 26.7 percent in INPV. The projected change in industry value for MHLF manufacturers would range from an increase of $38.3 million to a decrease of $3.6 million, or a net gain of 10.1 percent to net loss of 1.0 percent in INPV.

TSL 2 represents the highest magnetic ELs with a positive NPV, where the same ELs are required for indoor and outdoor fixtures. This TSL corresponds to a modeled magnetic ballast in 70 W, 150 W, 400 W, and 1000 W; and a commercially available magnetic ballast in 250 W. Indoor and outdoor fixtures at 1500 W would remain at baseline, with no new standards set. TSL 2 also prohibits the use of probe-start ballasts in new 1000 W fixtures.

After considering the analysis, the comments that DOE received on the NOPR, and the benefits and burdens of TSL 2, the Secretary has reached the following conclusion: TSL 2 offers the maximum improvement in efficiency that is technologically feasible and economically justified, and will result in significant conservation of energy. The benefits of energy savings, emissions reductions (both in physical reductions and the monetized value of those reductions), positive net economic savings (NPV) at discount rates of 3-percent and 7-percent at each representative equipment class would outweigh the potential reduction in INPV for manufacturers. Therefore, DOE today adopts energy conservation standards for metal halide lamp fixtures at TSL 2.

D. Final Standard Equations

As detailed in section VII.C of this notice, DOE is adopting TSL 2. TSL 2 sets an EL2 standard for indoor and outdoor metal halide fixtures for 50 W–150 W and 251 W–1000 W, and an EL1 standard for indoor and outdoor metal halide fixtures for 151 W–250 W. This creates a discontinuous combination of equations both above and below the 151 W–250 W equipment class. The discontinuity at 150 W occurs because fixtures below 150 W do not have to comply with EISA 2007, while those at 150 W and above are required to meet the 88 percent standard of EISA 2007. However, the discontinuity at 250 W occurs because TSL 2 represents EL1 from 151 W–250 W, but EL2 from 251 W–500 W. To maintain continuity, DOE developed new equations from 151 W–500 W. First, from 151 W–200 W, DOE maintained a flat 88 percent requirement. Then, from 201 W–500 W, DOE used one continuous power-law equation. Based on written comments from NEMA, lamps in this wattage range follow the same trend between lamp current squared (an indicator of ballast losses) and lamp wattage. (NEMA, No. 56 at p. 15) This implies that one equation can be used to represent the efficiency of all ballasts in this wattage range. The equation was created by connecting the 200 W ballasts with 0.880 efficiency with the 500 W EL2 efficiency (0.910) to ensure continuity with the EL equations for adjacent wattage ranges. The 250 W EL1 and 400 W EL2 representative units comply with the new equation. The resulting TSL 2 equations are shown in Table VII.51 below.

TABLE VII.51—TSL EQUATION

Wattage range	Efficiency level	EL equation	TSL equation
≥50 W and ≤100 W	EL2	1/(1+1.24×P^(−0.351)) †	1/(1+1.24×P^(−0.351))
>100 W and <150 W *	EL2	1/(1+1.24×P^(−0.351))	1/(1+1.24×P^(−0.351))
≥150 W ** and ≤250 W	EL1	≥150 W and ≤200 W: 0.88	≥150 W and ≤200 W: 0.88
		>200 W and ≤250 W: 0.000400×P + 0.800	>200 W and ≤250 W: 1/(1+0.876×P^(−0.351))
>250 W and ≤500 W	EL2	0.910	1/(1+0.876×P^(−0.351))
>500 W and ≤1000 W	EL2	>500 W and ≤750 W: 0.910	>500 W and ≤750 W: 0.910

TABLE VII.51—TSL EQUATION—Continued

Wattage range	Efficiency level	EL equation	TSL equation
		>750 W and ≤1000 W: 0.000104×P + 0.832	>750 W and ≤1000 W: 0.000104×P + 0.832

* Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† P is defined as the rated wattage of the lamp the MHLF is designed to operate.

DOE also created a continuous TSL equation for the non-representative equipment classes. As discussed in section V.C.11, the scaling factor to equipment classes tested at 480 V from equipment classes tested at all other voltages is 0.020 from 50 W–150 W and 0.010 from 151 W–1000 W. DOE applied these scaling factors to develop equations for non-representative equipment classes, with the exception of the 151 W–250 W and 251 W–500 W equipment classes. For wattages from 201 W–264 W, the scaled equation would be below 0.880. As detailed in section VII.E, DOE cannot adopt a standard below 0.880 for fixtures covered by EISA 2007. Thus the scaled TSL equation was adjusted to be 0.880 from 201–264 W, and the scaled equation is calculated as described previously at 265 W and above. The scaled TSL equation is shown in Table VII.52 below.

TABLE VII.52—TSL EQUATION

Wattage range	Efficiency level	TSL equation†
≥50 W and ≤100 W	EL2	(1/(1+1.24×P^(−0.351)) − 0.0200)
>100 W and <150 W*	EL2	(1/(1+1.24×P^(−0.351)) − 0.0200)
≥150 W** and ≤250 W	EL1	0.880
>250 W and ≤500 W	EL2	>250 W and <265 W: 0.880 ≥265 W and ≤500 W: (1/(1+0.876×P^(−0.351)) − 0.0100
>500 W and ≤1000 W	EL2	>500 W and ≤750 W: 0.900 >750 W and ≤1000 W: 0.000104×P + 0.822

* Includes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

** Excludes 150 W MHLFs exempted by EISA 2007, which are MHLFs rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

† P is defined as the rated wattage of the lamp the MHLF is designed to operate.

E. Backsliding

As discussed in section II.A of this notice, EPCA contains what is commonly known as an "anti-backsliding" provision, which mandates that the Secretary not prescribe any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) DOE evaluated amended standards in terms of ballast efficiency, which is the same metric that is currently used in energy conservation standards. Therefore, DOE compared the existing standards directly to the amended standards to confirm that they do not constitute backsliding.

The existing standards for ballast efficiency for MHLFs, established by EISA 2007, mandated that ballasts rated at wattages 150 W–500 W operate at a minimum of 88 percent efficiency if pulse-start, 94 percent if probe-start magnetic, 90 percent if non-pulse-start electronic 150 W–250 W, and 92 percent if non-pulse-start electronic 251 W–500 W. These standards excluded fixtures with regulated-lag ballasts, fixtures that use 480 V electronic ballasts, and fixtures that (1) are only rated for use with 150 W lamps; (2) are rated for use in wet locations; and (3) contain a ballast that is rated to operate above 50 °C. This rulemaking adopts standards for fixtures with ballasts rated at 50 W–1000 W, retains the exemptions for fixtures with regulated-lag ballasts or 480 V electronic ballasts, and removes the exemption for 150 W fixtures used in wet locations with ballasts rated that operate above 50 °C.

The Northwest Power and Conservation Council (NPCC) commented that because certain 150 W fixtures were exempt from EISA 2007, backsliding should not be a concern in this category. (NPCC, Public Meeting Transcript, No. 48 at pp. 112–114) DOE agrees with NPCC's assertion that backsliding is not an issue for 150 W fixtures rated for use with 150 W lamps, rated for wet locations, and rated to operate at temperatures greater than 50 °C. These exempted fixtures, along with fixtures that fall within wattage ranges that do not have existing federal energy conservation standards, cannot violate the backsliding provision as no standard currently exists.

As presented in the following table, DOE's adopted efficiency standards do not qualify as backsliding. In the 50 W–150 W[68] range, there are no existing federal efficiency standards. Thus, the standards set by DOE in this rulemaking for this wattage range are not backsliding, as they are prescribing a standard where there previously was not one. As stated previously, the 150 W ballasts currently exempted by EISA 2007 (those only rated for use with 150 W lamps, rated for wet locations, and rated to operate at temperatures greater than 50 °C) are not covered by any existing federal energy conservation standards, so the standards set for such

[68] This wattage range contains those fixtures that are rated only for 150 W lamps that are also rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and contain a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

ballasts are likewise not subject to backsliding. Similarly, in the 500 W–1000 W range, there are no existing federal energy conservation standards, so standards adopted in this rulemaking for that wattage range do not backslide. Finally, for the 150 W[69] −500 W range (not including the exempt 150 W fixtures), EISA 2007 prescribes the current standards. DOE is amending the standards for fixtures in this wattage range. The adopted standard changes with wattage, but always requires ballasts in new fixtures to be at least 88 percent efficient (88 percent efficiency for pulse-start ballasts is the least stringent of the various EISA 2007 requirements). If DOE's plotted efficiency level was lower than the standard prescribed by EISA 2007 for any ballast types or wattages (*e.g.*, 94 percent efficiency requirement for probe-start ballasts), then the EISA 2007 standard was given precedence and has been incorporated into today's rule without amendment, thus preventing any potential backsliding.

On the basis of this section, the standards adopted in this final rule are either higher than the existing standards, primarily because they set standards for previously unregulated fixtures, or match existing standards because if the EISA 2007 standards were higher than the efficiency levels calculated by DOE, then the EISA 2007 standard is retained. As such, the adopted standards do not decrease the minimum required energy efficiency of the covered equipment and, therefore, do not violate the anti-backsliding provision in EPCA.

TABLE VII.53—EXISTING FEDERAL EFFICIENCY STANDARDS AND EFFICIENCY STANDARDS ADOPTED IN THIS FINAL RULE

Designed to be operated with lamps of the following rated lamp wattage	Indoor/ outdoor***	Test input voltage‡	Existing standards (efficiency)	Adopted efficiency standards/equations† %
≥50 W and ≤100 W	Indoor	480 V	N/A	(1/(1+1.24×P^(−0.351))) − 0.020
≥50 W and ≤100 W	Indoor	All others	N/A	1/(1+1.24×P^(−0.351))
≥50 W and ≤100 W	Outdoor	480 V	N/A	(1/(1+1.24×P^(−0.351))) − 0.020
≥50 W and ≤100 W	Outdoor	All others	N/A	1/(1+1.24×P^(−0.351))
>100 W and <150 W*	Indoor	480 V	N/A	(1/(1+1.24×P^(−0.351))) − 0.020
>100 W and <150 W*	Indoor	All others	N/A	1/(1+1.24×P^(−0.351))
>100 W and <150 W*	Outdoor	480 V	N/A	(1/(1+1.24×P^(−0.351))) − 0.020
>100 W and <150 W*	Outdoor	All others	N/A	1/(1+1.24×P^(−0.351))
≥150 W** and ≤250 W	Indoor	480 V	Varies from 88% to 94% depending on ballast type.	0.880
≥150 W** and ≤250 W	Indoor	All others	Varies from 88% to 94% depending on ballast type.	For ≥150 W and ≤200 W: 0.880 For >200 W and ≤250 W: 1/(1+0.876×P^(−0.351))
≥150 W** and ≤250 W	Outdoor	480 V	Varies from 88% to 94% depending on ballast type.	0.880
≥150 W** and ≤250 W	Outdoor	All others	Varies from 88% to 94% depending on ballast type.	For ≥150 W and ≤200 W: 0.880 For >200 W and ≤250 W: 1/(1+0.876×P^(−0.351))
>250 W and ≤500 W	Indoor	480 V	Varies from 88% to 94% depending on ballast type.	For >250 W and <265 W: 0.880 For ≥265 W and ≤500 W;: (1/(1+0.876×P^(−0.351))—0.010
>250 W and ≤500 W	Indoor	All others	Varies from 88% to 94% depending on ballast type.	1/(1+0.876×P^(−0.351))
>250 W and ≤500 W	Outdoor	480 V	Varies from 88% to 94% depending on ballast type.	For >250 W and <265 W: 0.880 For ≥265 W and ≤500 W;: (1/(1+0.876×P^(−0.351)) − 0.010
>250 W and ≤500 W	Outdoor	All others	Varies from 88% to 94% depending on ballast type.	1/(1+0.876×P^(−0.351))
>500 W and ≤1000 W	Indoor	480 V	N/A	For >500 W and ≤750 W: 0.900 For >750 W and ≤1000 W: 0.000104×P+0.822 For >500 W and ≤1000 W: may not utilize a probe-start ballast
>500 W and ≤1000 W	Indoor	All others	N/A	For >500 W and ≤750 W: 0.910 For >750 W and ≤1000 W: 0.000104×P+0.832 For >500 W and ≤1000 W: may not utilize a probe-start ballast
>500 W and ≤1000 W	Outdoor	480 V	N/A	For >500 W and ≤750 W: 0.900 For >750 W and ≤1000 W: 0.000104×P+0.822 For >500 W and ≤1000 W: may not utilize a probe-start ballast
>500 W and ≤1000 W	Outdoor	All others	N/A	For >500 W and ≤750 W: 0.910

[69] This wattage range contains all covered fixtures that are rated only for 150 W lamps that are *not* also rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and do not also contain a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

TABLE VII.53—EXISTING FEDERAL EFFICIENCY STANDARDS AND EFFICIENCY STANDARDS ADOPTED IN THIS FINAL RULE—Continued

Designed to be operated with lamps of the following rated lamp wattage	Indoor/ outdoor***	Test input voltage‡	Existing standards (efficiency)	Adopted efficiency standards/equations† %
				For >750 W and ≤1000 W: 0.000104×P+0.832 For >500 W and ≤1000 W: may not utilize a probe-start ballast

*Includes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

**Excludes 150 W fixtures exempted by EISA 2007, which are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70–2002, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029–2007.

***DOE's definitions for "indoor" and "outdoor" MHLFs are described in section V.A.2.

†P is defined as the rated wattage of the lamp the fixture is designed to operate.

‡Input voltage for testing would be specified by the test procedures. Ballasts rated to operate lamps less than 150 W would be tested at 120 V, and ballasts rated to operate lamps ≥150 W would be tested at 277 V. Ballasts not designed to operate at either of these voltages would be tested at the highest voltage the ballast is designed to operate.

VIII. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Section 1(b)(1) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993), requires each agency to identify the problem that it intends to address, including, where applicable, the failures of private markets or public institutions that warrant new agency action, as well as to assess the significance of that problem. The problems that today's standards address are as follows:

There are external benefits resulting from improved energy efficiency of MHLFs that are not captured by the users of such equipment. These benefits include externalities related to environmental protection and energy security that are not reflected in energy prices, such as emissions of greenhouse gases. DOE attempts to quantify some of the external benefits through use of SCC values.

In addition, DOE has determined that today's regulatory action is an "economically significant regulatory action" under section 3(f)(1) of Executive Order 12866. Accordingly, section 6(a)(3) of the Executive Order requires that DOE prepare a regulatory impact analysis (RIA) on today's rule and that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget review this rule. DOE presented to OIRA for review the draft rule and other documents prepared for this rulemaking, including the RIA, and has included these documents in the rulemaking record. The assessments prepared pursuant to Executive Order 12866 can be found in the technical support document for this rulemaking.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281, Jan. 21, 2011). EO 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, OIRA has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, DOE believes that today's final rule is consistent with these principles, including the requirement that, to the extent permitted by law, benefits justify costs and that net benefits are maximized.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, and a final regulatory flexibility analysis (FRFA) for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required byE.O. 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (*http://energy.gov/gc/office-general-counsel*). DOE reviewed the August 2013 NOPR and today's final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

As a result of this review, DOE has prepared a FRFA for MHLFs and

ballasts, a copy of which DOE will transmit to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b). As presented and discussed below, the FRFA describes impacts on small MHLF and ballast manufacturers and discusses alternatives that could minimize these impacts.

A statement of the reasons for establishing the standards in today's final rule, and the objectives of and legal basis for these standards, are set forth elsewhere in the preamble and not repeated here.

This FRFA incorporates the IRFA and public comments DOE received on the IRFA and the economic impacts of the rule. DOE provides responses to these comments in the discussion below on the compliance impacts of the standards and elsewhere in the preamble. DOE modified the standards adopted in today's final rule in response to comments received as described in the preamble.

1. Description and Estimated Number of Small Entities Regulated

a. Methodology for Estimating the Number of Small Entities

For manufacturers of MHLFs and ballasts, the SBA has set a size threshold which defines those entities classified as "small businesses" for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. 65 FR 30836, 30850 (May 15, 2000), as amended at 65 FR 53533, 53545 (Sept. 5, 2000) and codified at 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.* MH ballast manufacturing is classified under NAICS 335311, "Power, Distribution and Specialty Transformer Manufacturing." The SBA sets a threshold of 750 employees or less for an entity to be considered as a small business for this category. MHLF manufacturing is classified under NAICS 335122, "Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing." The SBA sets a threshold of 500 employees or less for an entity to be considered as a small business for this category.

In the NOPR, DOE identified five small businesses that produce MH ballasts sold in the United States and can be considered small business manufacturers. For MHLFs, DOE identified approximately 54 small businesses that produce MHLFs sold in the United States and can be considered small business manufacturers. DOE did not receive any comments to suggest these estimates should be altered for the FRFA.

b. Manufacturer Participation

As stated in the August 2013 NOPR, DOE attempted to contact the small business manufacturers of MHLFs and ballasts it had identified. One small MH ballast manufacturer and two small MHLF manufacturers consented to being interviewed. DOE also obtained information about small business impacts while interviewing large manufacturers.

c. Metal Halide Ballast and Fixture Industry Structure

Ballasts. Five major MH ballast manufacturers with limited domestic production supply the vast majority of the MH ballast market. None of the five major manufacturers is a small business. The remaining market share is held by a few smaller domestic companies, only one of which has significant market share. Nearly all MH ballast production occurs abroad.

Fixtures. The majority of the MHLF market is supplied by six major manufacturers with sizeable domestic production. None of these major manufacturers is a small business. The remaining market share is held by several smaller domestic and foreign manufacturers. Most of the small domestic manufacturers produce MHLFs in the United States. Although none of the small businesses holds a significant market share individually, collectively these small businesses account for approximately a third of the market. See chapter 3 of this final rule TSD for further details on the MHLF and ballast markets.

d. Comparison Between Large and Small Entities

Ballasts. The five large MH ballast manufacturers typically offer a much wider range of designs of MH ballasts than small manufacturers do. MH ballasts can vary by start method, input voltage, wattage, and design. Often large MH ballast manufacturers will offer several different ballast options for each lamp wattage. Small manufacturers generally specialize in manufacturing only a handful of different ballast types and do not have the volume to support as wide a range of products as large manufacturers do. Three of the five small MH ballast manufacturers specialize in high-efficiency electronic ballasts and do not offer any magnetic ballasts. Some small MH ballast manufacturers offer a wide variety of lighting products, but others focus exclusively on MH ballasts.

Fixtures. The six large MHLF manufacturers typically serve large-scale commercial lighting markets, while small MHLF manufacturers tend to operate in niche lighting markets such as architectural and designer lighting. Small MHLF manufacturers also frequently fill custom orders that are much smaller in volume than large MHLF manufacturers' typical orders are. Because small MHLF manufacturers typically offer specialized products and cater to individual customers' needs, they can command higher markups than most large MHLF manufacturers. Like large MH ballast manufacturers, large MHLF manufacturers offer a wider range of MHLFs than small MHLF manufacturers. A small MHLF manufacturer may offer fewer than 50 models, while a large MHLF manufacturer may typically offer several hundred models. Almost all small MHLF manufacturers offer a variety of lighting products in addition to those covered by this rulemaking, such as fluorescent, incandescent, and LED fixtures.

2. Description and Estimate of Compliance Requirements

Ballasts. Because three of the five small MH ballast manufacturers offer only electronic ballasts that already meet the standards at TSL 2, the level established in today's final rule, DOE does not expect any product or capital conversion costs for these small MH ballast manufacturers. The fourth small MH ballast manufacturer offers a wide range of magnetic and electronic ballasts, so DOE does not expect this manufacturer's conversion costs to differ significantly from those of the large manufacturers. The fifth small ballast manufacturer currently offers a large variety of lighting products, but only two models of MH ballasts. Because it would likely invest in other parts of its business, this manufacturer stated to DOE that this rulemaking is unlikely to significantly affect them.

Fixtures. As previously stated, DOE identified approximately 54 small MHLF businesses affected by this rulemaking. Based on interviews with two of these manufacturers and examinations of product offerings on company Web sites, DOE believes that approximately one-fourth of these small businesses will not face any conversion costs because they offer very few MHLF models and would, therefore, focus on more substantial areas of their business. Of the remaining small businesses DOE identified, nearly two-thirds primarily

serve the architectural or specialty lighting markets. Because these products command higher prices and margins compared to the typical products offered by a large manufacturer, DOE believes that these small MHLF manufacturers will be able to pass on any necessary conversion costs to their customers without significantly impacting their businesses.

Philips commented that they believe small MHLF manufacturers might not be able to pass cost increases due to standards, because in the architectural and specialty lighting areas, LEDs are becoming extremely cost competitive. (Philips, Public Meeting Transcript, No. 48 at p. 289) Based on small business fixture manufacturer interviews, DOE believes that many of the architectural and specialty lighting fixtures are custom made orders and the conversion costs for these MHLFs would likely be small. While DOE does acknowledge that the MH ballasts used in these MHLFs could increase in price, which would result in a higher priced MHLF for customers, these small fixture manufacturers stated they also manufacture and sell LED fixtures to meet any customer's needs.

The remaining small MHLF manufacturers (roughly 14 in number) could be differentially impacted by today's established standards. These manufacturers operate partially in industrial and commoditized markets in which it may be more difficult to pass on any disproportionate costs to their customers. The impacts could be relatively greater for a typical small MHLF manufacturer because of the far lower production volumes and the relatively fixed nature of the R&D and capital resources required per fixture family.

Based on interviews, however, DOE anticipates that small manufacturers would take steps to mitigate the costs required to meet new and amended energy conservation standards. DOE believes that under the established standards, small MHLF businesses would likely selectively upgrade existing product lines to offer equipment that is in high demand or offers a strategic advantage for that company. Small manufacturers could then spread out further investments over a longer time period by not upgrading all product lines prior to the compliance date.

Additionally, DOE does not expect that small MHLF manufacturers would be significantly burdened by compliance requirements. As discussed in section IV.A, the standards adopted in this final rule provide simplifying amendments to the current testing and reporting procedures. DOE is only mandating testing at a single input voltage for MHLFs Because DOE selected the least burdensome input voltage option, DOE concludes that regulations in this final rule would not have a significantly adverse impact on the testing burden of small manufacturers.

The existing test procedures already dictate that testing for certification requires a sample of at least four MHLFs for compliance. DOE is not proposing to change this minimum sample size, and as such, does not find an increased testing burden on small manufacturers.

DOE did not receive any comments suggesting new and amended energy conservation standards would significantly impact small MHLF and ballast manufacturers.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being established today.

4. Significant Alternatives to the Rule

Section VII.B.2 analyzes impacts on small businesses that would result from DOE's adopted rule. In addition to the other TSLs being considered, the final rule TSD includes an RIA. For MHLFs, the RIA discusses the following policy alternatives: (1) No new regulatory action; (2) consumer tax incentives; (3) manufacturer tax incentives; (4) performance standards; (5) consumer rebates; (6) manufacturer rebates; (7) voluntary energy efficiency targets; (8) early replacement; and (9) bulk government purchases. While these alternatives may mitigate to some varying extent the economic impacts on small entities compared to the standards, DOE determined that the energy savings of these alternatives are significantly smaller than those that would be expected to result from the adopted standard levels. Accordingly, DOE is declining to adopt any of these alternatives and is adopting the standards set forth in this rulemaking. (See chapter 18 of the final rule TSD for further detail on the policy alternatives DOE considered.)

As previously stated, DOE did not receive any comments suggesting new and amended energy conservation standards would significantly impact small MHLF and ballast manufacturers.

C. Review Under the Paperwork Reduction Act

Manufacturers of MHLFs must certify to DOE that their equipment complies with any applicable energy conservation standards. In certifying compliance, manufacturers must test their equipment according to DOE test procedures for MHLFs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including MHLFs. (76 FR 12422 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. See 10 CFR Part 1021, App. B, B5.1(b); 1021.410(b) and Appendix B, B(1)–(5). The rule fits within the category of actions because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this rule. DOE's CX determination for this rule is available at *http://cxnepa.energy.gov/*.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism." 64 FR 43255 (Aug. 10, 1999) imposes certain requirements on federal agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. The Executive Order requires agencies to

examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. EPCA governs and prescribes federal preemption of state regulations as to energy conservation for the equipment that is the subject of today's final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," imposes on federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each federal agency to assess the effects of federal regulatory actions on state, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a new and amended regulatory action likely to result in a rule that may cause the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a federal agency to develop an effective process to permit timely input by elected officers of state, local, and Tribal governments on a "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/gc/office-general-counsel.*

DOE has concluded that this final rule would likely require expenditures of $100 million or more on the private sector. Such expenditures may include: (1) Investment in research and development and in capital expenditures by MHLFs manufacturers in the years between the final rule and the compliance date for the new standards, and (2) incremental additional expenditures by customers to purchase higher-efficiency MHLFs, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the final rule. 2 U.S.C. 1532(c). The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of the notice of final rulemaking and the "Regulatory Impact Analysis" section of the TSD for this final rule respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. 2 U.S.C. 1535(a). DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(hh), and (o), 6317(a), today's final rule would establish energy conservation standards for MHLFs that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in the "Regulatory Impact Analysis" section of the TSD for today's final rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for federal agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed

today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" 66 FR 28355 (May 22, 2001), requires federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that today's regulatory action, which sets forth energy conservation standards for MHLFs, is not a significant energy action because the new and amended standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on the final rule.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are "influential scientific information," which the Bulletin defines as scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions. 70 FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The "Energy Conservation Standards Rulemaking Peer Review Report" dated February 2007 has been disseminated and is available at the following Web site: *www1.eere.energy.gov/buildings/appliance_standards/peer_review.html.*

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

IX. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's final rule.

List of Subjects in 10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, and Small businesses.

Issued in Washington, DC, on January 27, 2014.

David T. Danielson,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE amends part 431 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 431.322 is amended by adding in alphabetical order definitions for "general lighting application" "high-frequency electronic metal halide ballast," and "nonpulse-start electronic ballast," to read as follows:

§ 431.322 Definitions concerning metal halide ballasts and fixtures.

* * * * *

General lighting application means lighting that provides an interior or exterior area with overall illumination.

High-frequency electronic metal halide ballast means an electronic ballast that operates a lamp at an output frequency of 1000 Hz or greater.

* * * * *

Nonpulse-start electronic ballast means an electronic ballast with a starting method other than pulse-start.

* * * * *

■ 3. Section 431.324 is amended by adding paragraph (b)(1)(iii) and revising paragraphs (b)(3) and (c)(1) to read as follows:

§ 431.324 Uniform test method for the measurement of energy efficiency and standby mode energy consumption of metal halide ballasts.

* * * * *

(b) * * *

(1) * * *

(iii) *Input Voltage for Tests.* For ballasts designed to operate lamps rated less than 150 W that have 120 V as an available input voltage, testing shall be performed at 120 V. For ballasts designed to operate lamps rated less than 150 W that do not have 120 V as an available voltage, testing shall be performed at the highest available input voltage. For ballasts designed to operate lamps rated greater than or equal to 150 W that have 277 V as an available input voltage, testing shall be conducted at 277 V. For ballasts designed to operate lamps rated greater than or equal to 150 W that do not have 277 V as an available input voltage, testing shall be conducted at the highest available input voltage.

* * * * *

(3) *Efficiency Calculation.* The measured lamp output power shall be divided by the measured ballast input power to determine the percent efficiency of the ballast under test to three significant figures.

(i) A fractional number at or above the midpoint between two consecutive decimal places shall be rounded up to the higher of the two decimal places; or

(ii) A fractional number below the midpoint between two consecutive decimal places shall be rounded down to the lower of the two decimal places.

(c) * * *

(1) *Test Conditions.* (i) The power supply and ballast test conditions with the exception of input voltage shall all conform to the requirements specified in section 4.0, "General Conditions for Electrical Performance Tests," of the ANSI C82.6 (incorporated by reference; see § 431.323). Ambient temperatures for the testing period shall be maintained at 25 °C ± 5 °C. Send a signal to the ballast instructing it to have zero light output using the appropriate ballast communication protocol or system for the ballast being tested.

(ii) *Input Voltage for Tests.* For ballasts designed to operate lamps rated less than 150 W that have 120 V as an available input voltage, ballasts are to be tested at 120 V. For ballasts designed to operate lamps rated less than 150 W that do not have 120 V as an available voltage, ballasts are to be tested at the highest available input voltage. For ballasts designed to operate lamps rated greater than or equal to 150 W that have 277 V as an available input voltage, ballasts are to be tested at 277 V. For ballasts designed to operate lamps rated greater than or equal to 150 W that do not have 277 V as an available input voltage, ballasts are to be tested at the highest available input voltage.

* * * * *

■ 4. Section 431.326 is amended by adding paragraphs (c), (d), and (e) to read as follows:

§ 431.326 Energy conservation standards and their effective dates.

* * * * *

(c) Except when the requirements of paragraph (a) of this section are more stringent (*i.e.*, require a larger minimum efficiency value) or as provided by paragraph (e) of this section, each metal halide lamp fixture manufactured on or after February 10, 2017, must contain a metal halide ballast with an efficiency not less than the value determined from the appropriate equation in the following table:

Designed to be operated with lamps of the following rated lamp wattage	Tested input voltage‡‡	Minimum standard equation†† %
≥50 W and ≤100 W	Tested at 480 V	(1/(1+1.24×P^(−0.351))) − 0.020††
≥50 W and ≤100 W	All others	1/(1+1.24×P^(−0.351))
>100 W and <150† W	Tested at 480 V	(1/(1+1.24×P^(−0.351))) − 0.020
>100 W and <150† W	All others	1/(1+1.24×P^(−0.351))
≥150‡ W and ≤250 W	Tested at 480 V	0.880
≥150‡ W and ≤250 W	All others	For ≥150 W and ≤200 W: 0.880 For >200 W and ≤250 W: 1/(1+0.876×P^(−0.351))
>250 W and ≤500 W	Tested at 480 V	For >250 and <265 W: 0.880 For ≥265 W and ≤500 W: (1/(1+0.876×P^(−0.351)) − 0.010
>250 W and ≤500 W	All others	1/(1+0.876×P^(−0.351))
>500 W and ≤1000 W	Tested at 480 V	For >500 W and ≤750 W: 0.900 For >750 W and ≤1000 W: 0.000104×P+0.822 For >500 W and ≤1000 W: may not utilize a probe-start ballast
>500 W and ≤1000 W	All others	For >500 W and ≤750 W: 0.910 For >750 W and ≤1000 W: 0.000104×P+0.832 For >500 W and ≤1000 W: may not utilize a probe-start ballast

† Includes 150 W fixtures specified in paragraph (b)(3) of this section, that are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70 (incorporated by reference, see § 431.323), section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029 (incorporated by reference, see § 431.323).

‡ Excludes 150 W fixtures specified in paragraph (b)(3) of this section, that are fixtures rated only for 150 W lamps; rated for use in wet locations, as specified by the NFPA 70, section 410.4(A); and containing a ballast that is rated to operate at ambient air temperatures above 50 °C, as specified by UL 1029.

†† P is defined as the rated wattage of the lamp the fixture is designed to operate.

‡‡ Tested input voltage is specified in 10 CFR 431.324.

(d) Except as provided in paragraph (e) of this section, metal halide lamp fixtures manufactured on or after February 10, 2017, that operate lamps with rated wattage >500 W to ≤1000 W must not contain a probe-start metal halide ballast.

(e) The standards described in paragraphs (c) and (d) of this section do not apply to—

(1) Metal halide lamp fixtures with regulated-lag ballasts;

(2) Metal halide lamp fixtures that use electronic ballasts that operate at 480 volts; and

(3) Metal halide lamp fixtures that use high-frequency electronic ballasts.

[FR Doc. 2014–02356 Filed 2–7–14; 8:45 am]

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Part III

Department of Energy

10 CFR Part 430
Energy Conservation Program: Energy Conservation Standards for External Power Supplies; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2008–BT–STD–0005]

RIN 1904–AB57

Energy Conservation Program: Energy Conservation Standards for External Power Supplies

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: Pursuant to the Energy Policy and Conservation Act of 1975 (EPCA), as amended, today's final rule amends the energy conservation standards that currently apply to certain external power supplies and establishes new energy conservation standards for other external power supplies that are currently not required to meet such standards. Through its analysis, DOE has determined that these changes satisfy EPCA's requirements that any new and amended energy conservation standards for these products result in the significant conservation of energy and be both technologically feasible and economically justified.

DATES: The effective date of this rule is April 11, 2014. Compliance with the new and amended standards established for EPSs in today's final rule is February 10, 2016.

The incorporation by reference of a certain publication listed in this rule is approved by the Director of the Federal Register on April 11, 2014.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at regulations.gov. All documents in the docket are listed in the regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket can be accessed from the regulations.gov homepage by searching for Docket ID EERE–2008–BT–STD–0005. The regulations.gov Web page contains simple instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *battery_chargers_and_external_power_supplies@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *michael.kido@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This final rule incorporates by reference into part 430 the following industry standard:

International Efficiency Marking Protocol for External Power Supplies, Version 3.0

The above referenced document has been added to the docket for this rulemaking and can be downloaded from Docket EERE–2008–BT–STD–0005 on *Regulations.gov.*

The document is discussed in section IV.O of this notice.

Table of Contents

I. Summary of the Final Rule and Its Benefits

Today's notice announces the Department of Energy's (DOE's) amended and new energy conservation standards for certain classes of external power supplies (EPSs). These standards, which are based on a series of mathematical equations that vary based on output power, will affect a wide variety of EPSs used in a wide variety of consumer applications.

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles.[2] Pursuant to EPCA, any new and amended energy conservation standard that DOE prescribes for certain products, such as EPSs, shall be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new and amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) In accordance with these provisions, DOE is amending the standards for certain EPSs—those devices that are already regulated by standards enacted by Congress in 2007—and establishing new standards for EPSs that have not yet been regulated by DOE. These standards, which prescribe a minimum average efficiency during active mode (i.e. when an EPS is plugged into the main electricity supply and is supplying power in response to a load demand from another connected device) and a maximum power consumption level during no-load mode (i.e. when an EPS is plugged into the main electricity supply but is not supplying any power in response to a demand load from another connected device), are expressed as a function of the nameplate output power (i.e. the power output of the EPS). These standards are shown in Table I–1, and will apply to all products listed in Table I.1 and manufactured in, or imported into, the United States starting on February 10, 2016.

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (Dec. 18, 2012).

Table I-1. Energy Conservation Standards for Direct Operation EPSs* (Compliance Starting **February 10, 2016.**)

Single-Voltage External AC-DC Power Supply, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	≤ 0.100
1 W $< P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	≤ 0.100
49 W $< P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
Single-Voltage External AC-DC Power Supply, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	≤ 0.100
1 W $< P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	≤ 0.100
49 W $< P_{out} \leq 250$ W	≥ 0.870	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
Single-Voltage External AC-AC Power Supply, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	≤ 0.210
1 W $< P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	≤ 0.210
49 W $< P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
Single-Voltage External AC-AC Power Supply, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	≤ 0.210
1 W $< P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	≤ 0.210

49 W < P_{out} ≤ 250 W	≥ 0.870	≤ 0.210
P_{out} > 250 W	≥ 0.875	≤ 0.500
Multiple-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
P_{out} ≤ 1 W	≥ 0.497 × P_{out} + 0.067	≤ 0.300
1 W < P_{out} ≤ 49 W	≥ 0.075 × ln(P_{out}) + 0.561	≤ 0.300
P_{out} > 49 W	≥ 0.860	≤ 0.300

* Excludes any device that requires Federal Food and Drug Administration (FDA) listing and approval as a medical device in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)) and any AC-DC EPS with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps that charges the battery of a product that is fully or primarily motor operated. Additionally, consistent with EPCA, certain EPSs used for certain life safety and security equipment do not need to meet the no-load mode requirements.

The new and amended standards being adopted today apply to all direct operation EPSs, both Class A and non-Class A, with the exceptions noted in the footnote to Table I–1. These exemptions are discussed in more detail in Section IV.A.2.d and Section B.5. Note that the standards established by Congress for Class A EPSs will continue in force for all Class A EPSs, including indirect operation EPSs. Therefore, all indirect operation Class A EPSs must continue to meet the standards established by Congress at efficiency level IV (discussed in Section II.B.1), while direct operation Class A EPSs will be required to meet the more stringent standards being adopted today.

A. Benefits and Costs to Consumers

Table I–2 presents DOE's evaluation of the economic impacts of today's standards on EPS consumers, as measured by the average life-cycle cost (LCC) savings, the median payback period, and the average lifetime. The average LCC savings are positive and the median payback periods are less than the average lifetimes for all product classes for which consumers are impacted by the standards.

Table I-2 Impacts of Today's Standards on Consumers of EPSs

Representative Unit	Average LCC Savings (2012$)	Median Payback Period (years)	Average Lifetime (years)
2.5W AC-DC, Basic Voltage	0.17	3.7	4.8
18W AC-DC, Basic Voltage	0.81	2.9	4.5
60W AC-DC, Basic Voltage	0.90	1.3	4.1
120W AC-DC, Basic Voltage	0.79	1.7	3.7
203W Multiple-Voltage	2.38	4.0	5.0
345W High-Power	142.18	0.0	10.0

B. Impact on Manufacturers

The industry net present value (INPV) is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2013 to 2044). Using a real discount rate of 7.1 percent, DOE estimates that the industry net present value (INPV) for manufacturers of EPSs is $274.0 million in 2012$. Under today's standards, DOE expects that manufacturers may lose up to 18.7 percent of their INPV, which is approximately $51.2 million. Additionally, based on DOE's interviews with the manufacturers of EPSs no domestic OEM EPS manufacturers were identified and therefore, DOE does not expect any plant closings or significant loss of employment.

C. National Benefits[3]

DOE's analyses indicate that today's standards would save a significant amount of energy. The lifetime savings for EPSs purchased in the 30-year period that begins in the year of compliance with new and amended standards (2015–2044) amount to 0.94 quads. The annual energy savings in 2030 amount to 0.15 percent of total residential energy use in 2012.[4]

The estimated cumulative net present value (NPV) of total consumer costs and savings of today's standards for EPSs ranges from $1.9 billion (at a 7-percent discount rate) to $3.8 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product costs for products purchased in 2015–2044.

In addition, today's standards are projected to yield significant environmental benefits. The energy savings would result in cumulative greenhouse gas emission reductions of approximately 47.0 million metric tons (Mt)[5] of carbon dioxide (CO_2), 81.7 thousand tons of sulfur dioxide (SO_2), 15.0 thousand tons of nitrogen oxides (NO_X) and 0.1 tons of mercury (Hg).[6] Through 2030, the estimated energy savings would result in cumulative emissions reductions of 23.6 Mt of CO_2.

The value of the CO_2 reductions is calculated using a range of values per metric ton of CO_2 (otherwise known as the Social Cost of Carbon, or SCC) developed and recently updated by an interagency process.[7] The derivation of the SCC values is discussed in section IV.L. DOE estimates that the net present monetary value of the CO_2 emissions reductions is between $0.4 billion and $4.7 billion. DOE also estimates that the net present monetary value of the NO_X emissions reductions is $0.014 billion at a 7-percent discount rate and $0.024 billion at a 3-percent discount rate.[8]

Table I–3 summarizes the national economic costs and benefits expected to result from today's standards for EPSs.

[3] All monetary values in this section are expressed in 2012 dollars and are discounted to 2013.

[4] Total residential energy use in 2012 was 20.195 quads. See: *http://www.eio.gov/totolenergy/doto/monthly/?src=Totol-f3# consumption*

[5] A metric ton is equivalent to 1.1 short tons. Results for NO_X and Hg are presented in short tons.

[6] DOE calculated emissions reductions relative to the *Annuol Energy Outlook 2013* (*AEO 2013*) Reference case, which generally represents current legislation and environmental regulations for which implementing regulations were available as of December 31, 2012.

[7] *Technicol Updote of the Sociol Cost of Corbon for Regulotory Impoct Anolysis Under Executive Order 12866.* Interagency Working Group on Social Cost of Carbon, United States Government. May 2013; revised November 2013. *http://www.whitehouse.gov/sites/defoult/files/omb/ossets/inforeg/technicol-updote-sociol-cost-of-corbon-for-regulotor-impoct-onolysis.pdf*

[8] DOE is currently investigating valuation of avoided Hg and SO_2 emissions.

Table I-3. Summary of National Economic Benefits and Costs of EPS Energy Conservation Standards, Present Value for EPS Shipped in 2015-2044 in Billion 2012$

Category	Present Value (Billion 2012$)	Discount Rate
Benefits		
Operating Cost Savings	3.9	7%
	7.1	3%
CO_2 Reduction Monetized Value ($11.8/t case)*	0.4	5%
CO_2 Reduction Monetized Value ($39.7/t case)*	1.5	3%
CO_2 Reduction Monetized Value ($61.2/t case)*	2.4	2.5%
CO_2 Reduction Monetized Value ($117/t case)*	4.7	3%
NO_X Reduction Monetized Value (at $2,639/ton)**	0.014	7%
	0.024	3%
Total Benefits†	5.5	7%
	8.6	3%
Costs		
Incremental Installed Costs	2.0	7%
	3.3	3%
Net Benefits		
Including CO_2 and NO_X Reduction Monetized Value†	3.5	7%
	5.4	3%

* The interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth set, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, is included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The values in parentheses represent the SCC in 2015. The SCC time series incorporate an escalation factor.

** The value represents the average of the low and high NO_X values used in DOE's analysis.

† Total Benefits for both the 3% and 7% cases are derived using the series corresponding to average SCC with 3-percent discount rate.

The benefits and costs of today's standards, for products sold in 2015–2044, can also be expressed in terms of annualized values. The annualized monetary values are the sum of (1) the annualized national economic value of the benefits from operating the product (consisting primarily of operating cost savings from using less energy, minus increases in equipment purchase and installation costs, which is another way of representing consumer NPV), plus (2) the annualized monetary value of the benefits of emission reductions, including CO_2 emission reductions.[9]

Although adding the value of consumer savings to the value of emission reductions provides a valuable perspective, two issues should be considered. First, the national operating cost savings are domestic U.S. consumer monetary savings that occur as a result of market transactions, while the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and CO_2 savings are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of EPSs shipped in 2015–2044. The SCC values, on the other hand, reflect the present value of all future climate-related impacts resulting from the emission of one metric ton of carbon dioxide in each year. These impacts continue well beyond 2100.

[9] DOE used a two-step calculation process to convert the time-series of costs and benefits into annualized values. First, DOE calculated a present value in 2013, the year used for discounting the NPV of total consumer costs and savings, for the time-series of costs and benefits using discount rates of three and seven percent for all costs and benefits except for the value of CO_2 reductions. For the latter, DOE used a range of discount rates, as shown in Table I.3. From the present value, DOE then calculated the fixed annual payment over a 30-year period (2013 through 2042) that yields the same present value. The fixed annual payment is the annualized value. Although DOE calculated annualized values, this does not imply that the time-series of cost and benefits from which the annualized values were determined is a steady stream of payments.

Estimates of annualized benefits and costs of today's standards are shown in Table I–4. The results under the primary estimate are as follows. Using a 7-percent discount rate for benefits and costs other than CO_2 reduction, for which DOE used a 3-percent discount rate along with the average SCC series that uses a 3-percent discount rate, the cost of the standards in today's rule is $147 million per year in increased equipment costs to consumers, while the benefits are $293 million per year in reduced equipment operating costs to consumers, $77 million in CO_2 reductions, and $1.1 million in reduced NO_X emissions. In this case, the net benefit amounts to $223 million per year. Using a 3-percent discount rate for all benefits and costs and the average SCC series, the cost of the standards in today's rule is $162 million per year in increased equipment costs, while the benefits are $350 million per year in reduced operating costs, $77 million in CO_2 reductions, and $1.2 million in reduced NO_X emissions. In this case, the net benefit amounts to $266 million per year.

Table I-4 Annualized Benefits and Costs of New and Amended Standards for EPSs, in Million 2012$

	Discount Rate	Primary Estimate*	Low Net Benefits Estimate*	High Net Benefits Estimate*
		million 2012$/year		
Benefits				
Consumer Operating Cost Savings	7%	293	292	298
	3%	350	347	356
CO_2 Reduction ($11.8/t case)**	5%	22	22	22
CO_2 Reduction ($39.7/t case)**	3%	77	77	77
CO_2 Reduction ($61.2/t case)**	2.5%	114	114	114
CO_2 Reduction ($117/t case)**	3%	235	235	235
NO_X Reduction at $2,639/ton**	7%	1.06	1.06	1.06
	3%	1.20	1.20	1.20
Total Benefits†	7% plus CO_2 range	316 to 529	315 to 528	321 to 534
	7%	371	369	375
	3% plus CO_2 range	373 to 586	370 to 583	379 to 592
	3%	428	425	434
Costs				
Consumer Incremental Product Costs	7%	147	147	94
	3%	162	162	96
Net Benefits				
Total†	7% plus CO_2 range	169 to 382	168 to 381	227 to 440
	7%	223	222	281
	3% plus CO_2 range	211 to 424	209 to 422	284 to 497
	3%	266	263	338

* This table presents the annualized costs and benefits associated with EPSs shipped in 2015 - 2044. These results include benefits to consumers which accrue after 2044 from EPSs purchased from 2015 - 2044. Costs incurred by manufacturers, some of which may be incurred prior to 2015 in preparation for the rule, are not directly included, but are indirectly included as part of incremental equipment costs. The Primary, Low Benefits, and High Benefits Estimates utilize projections of energy prices from the AEO 2013 Reference case, Low Estimate, and High Estimate, respectively. In addition, incremental product costs reflect a constant rate for projected product price trends in the Primary Estimate, a constant rate for projected product price trends in the Low Benefits Estimate, and a declining rate for projected product price trends in the High Benefits Estimate. The methods used to derive projected price trends are explained in section IV.F.1.

** The interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the three integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth set, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, is included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The values in parentheses represent the SCC in 2015. The SCC time series incorporate an escalation factor. The value for NO_X is the average of the low and high values used in DOE's analysis.

† Total Benefits for both the 3-percent and 7-percent cases are derived using the series corresponding to average SCC with 3-percent discount rate. In the rows labeled "7% plus CO_2 range" and "3% plus CO_2 range," the operating cost and NO_X benefits are calculated using the labeled discount rate, and those values are added to the full range of CO_2 values.

D. Conclusion

Based on the analyses culminating in this final rule, DOE found the benefits to the Nation of the standards (energy savings, consumer LCC savings, positive NPV of consumer benefit, and emission reductions) outweigh the burdens (loss of INPV and LCC increases for some users of these products). DOE has concluded that the standards in today's final rule represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in significant conservation of energy.

II. Introduction

The following section briefly discusses the statutory authority underlying today's final rule, as well as some of the relevant historical background related to the establishment of standards for EPSs.

A. Authority

Title III, Part B [10] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as "covered products"),[11] which includes the types of EPSs that are the subject of this rulemaking. (42 U.S.C. 6295(u)) (DOE notes that under 42 U.S.C. 6295(m), the agency must periodically review its already established energy conservation standards for a covered product. Under this requirement, the next review that DOE would need to conduct must occur no later than six years from the issuance of a final rule establishing or amending a standard for a covered product.)

Pursuant to EPCA, DOE's energy conservation program for covered products consists essentially of four parts: (1) Testing; (2) labeling; (3) the establishment of Federal energy conservation standards; and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling, and DOE implements the remainder of the program. The labeling of EPSs, however, is one of the few exceptions for which either agency may establish requirements as needed. See 42 U.S.C. 6294(a)(5)(A). Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6293) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. *Id.* The DOE test procedures for EPSs currently appear at title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix Z. See also 76 FR 31750 (June 1, 2011) (finalizing the most recent amendment to the test procedures for EPSs).

DOE must follow specific statutory criteria for prescribing new and amended standards for covered products. As indicated above, any new and amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)) Moreover, DOE may not prescribe a standard: (1) For certain products, including EPSs, if no test procedure has been established for the product, or (2) if DOE determines by rule that the new and amended standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a new and amended standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard and by considering, to the greatest extent practicable, the following seven factors:

1. The economic impact of the standard on manufacturers and consumers of the products subject to the standard;
2. The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the imposition of the standard;
3. The total projected amount of energy, or as applicable, water, savings likely to result directly from the imposition of the standard;
4. Any lessening of the utility or the performance of the covered products likely to result from the imposition of the standard;
5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard;
6. The need for national energy and water conservation; and
7. Other factors the Secretary of Energy (Secretary) considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

EPCA, as codified, also contains what is known as an "anti-backsliding" provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C.

[10] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[11] All references to EPCA in this document refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (Dec. 18, 2012).

6295(o)(1)) Also, the Secretary may not prescribe a new and amended standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States of any covered product type (or class) having performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. See 42 U.S.C. 6295(o)(2)(B)(iii).

Additionally, 42 U.S.C. 6295(q)(1) specifies requirements when promulgating a standard for a type or class of covered product that has two or more subcategories. DOE must specify a different standard level than that which applies generally to such type or class of product for any group of covered products that have the same function or intended use if DOE determines that products within such group (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Federal energy conservation requirements generally preempt State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6297(d). The energy conservation standards established in this rule will preempt relevant State laws or regulations on February 10, 2016.

Also, pursuant to the amendments contained in section 310(3) of EISA 2007, any final rule for new and amended energy conservation standards promulgated after July 1, 2010, are required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into the standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures and standards for EPSs address standby mode and off mode energy use, as do the standards adopted in this final rule.

Finally, Congress created a series of energy conservation requirements for certain types of EPSs—those EPSs that meet the "Class A" criteria. See 42 U.S.C. 6295(u)(3) (establishing standards for Class A EPSs) and 6291(36)(C) (defining what a Class A EPS is). Congress clarified the application of these standards in a subsequent revision to EPCA by creating an exclusion for certain types of Class A EPSs. In particular, EPSs that are designed to be used with security or life safety alarm or surveillance system that are manufactured prior to 2017 are not required to meet the no-load mode requirements. See 42 U.S.C. 6295(u)(3)(E) (detailing criteria for satisfying the exclusion requirements). The standards in today's final rule are consistent with these Congressionally-enacted provisions.

B. Background

1. Current Standards

Section 301 of EISA 2007 established minimum energy conservation standards for Class A EPSs, which became effective on July 1, 2008. (42 U.S.C. 6295(u)(3)(A)). Class A EPSs are types of EPSs defined by Congress that meet certain design criteria and that are not devices regulated by the Food and Drug Administration as medical devices or that power the charger of a detachable battery pack or the battery of a product that is fully or primarily motor operated. See 42 U.S.C. 6291(36)(C)(i)–(ii). The current standards for Class A EPSs are set forth in Table II.1.

Table II-1: Federal Energy Efficiency Standards for Class A EPSs

Active Mode	
Nameplate Output Power	**Minimum Efficiency (decimal equivalent of a percentage)**
< 1 Watt	0.5 × (nameplate_output)
1–51 Watts	0.5 + 0.09 × **ln**(nameplate_output)
> 51 Watts	0.85
No-Load Mode	
Nameplate Output Power	**Maximum Power Consumption**
≤ 250 Watts	0.5 Watts

Currently, there are no Federal energy conservation standards for EPSs falling outside of Class A.

2. History of Standards Rulemaking for EPSs

Section 135 of the Energy Policy Act of 2005 (EPACT 2005), Public Law 109–58 (Aug. 8, 2005), amended sections 321 and 325 of EPCA by defining the term "external power supply." That provision also directed DOE to prescribe test procedures related to the energy consumption of EPSs and to issue a final rule that determines whether

energy conservation standards shall be issued for EPSs or classes of EPSs. (42 U.S.C. 6295(u)(1)(A) and (E))

On December 8, 2006, DOE complied with the first of these requirements by publishing a final rule that prescribed test procedures for a variety of products, including EPSs. 71 FR 71340. See also 10 CFR part 430, Subpart B, Appendix Z ("Uniform Test Method for Measuring the Energy Consumption of External Power Supplies") (codifying the EPS test procedure).

On December 19, 2007, Congress enacted EISA 2007, which, among other things, amended sections 321, 323, and 325 of EPCA (42 U.S.C. 6291, 6293, and 6295). As part of these amendments, EISA 2007 supplemented the EPS definition, which the statute defines as an external power supply circuit "used to convert household electric current into DC current or lower-voltage AC current to operate a consumer product." (42 U.S.C. 6291(36)(A)) In particular, Section 301 of EISA 2007 created a subset of EPSs called "Class A External Power Supplies," which consists of, among other elements, those EPSs that can convert to only 1 AC or DC output voltage at a time and have a nameplate output power of no more than 250 watts (W). The Class A definition, as noted earlier, excludes any device requiring Federal Food and Drug Administration (FDA) listing and approval as a medical device in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)) along with devices that power the charger of a detachable battery pack or that charge the battery of a product that is fully or primarily motor operated. (42 U.S.C. 6291(36)(C)) Section 301 of EISA 2007 also established energy conservation standards for Class A EPSs that became effective on July 1, 2008, and directed DOE to conduct an energy conservation standards rulemaking to review those standards.

Additionally, section 309 of EISA 2007 amended section 325(u)(1)(E) of EPCA (42 U.S.C. 6295(u)(1)(E)) by directing DOE to issue a final rule prescribing energy conservation standards for battery chargers or classes of battery chargers or to determine that no energy conservation standard is technologically feasible and economically justified. To satisfy these requirements, along with those for EPSs, as noted later, DOE chose to bundle the rulemakings for these separate products together into a single rulemaking effort. The rulemaking requirements contained in sections 301 and 309 of EISA 2007 also effectively superseded the prior determination analysis that EPACT 2005 required DOE to conduct.

Section 309 of EISA 2007 also instructed DOE to issue a final rule to determine whether DOE should issue energy conservation standards for EPSs or classes of EPSs by no later than two years after EISA 2007's enactment. (42 U.S.C. 6295(u)(1)(E)(i)(I)) Because Congress had already set standards for Class A devices, DOE interpreted this determination requirement as applying solely to assessing whether energy conservation standards would be warranted for EPSs that fall outside of the Class A definition, *i.e.*, non-Class A EPSs. Non-Class A EPSs include those devices that (1) have a nameplate output power greater than 250 watts, (2) are able to convert to more than one AC or DC output voltage simultaneously, and (3) are specifically excluded from coverage under the Class A EPS definition in EISA 2007 by virtue of their application (i.e. EPSs used with medical devices or that power chargers of detachable battery packs or batteries of products that are motor-operated).[12]

Finally, section 310 of EISA 2007 established definitions for active, standby, and off modes, and directed DOE to amend its existing test procedures for EPSs to measure the energy consumed in standby mode and off mode. (42 U.S.C. 6295(gg)(2)(B)(i)) Consequently, DOE published a final rule incorporating standby- and off-mode measurements into the DOE test procedure. See 74 FR 13318 (March 27, 2009) DOE later amended its test procedure for EPSs by including a measurement method for multiple-voltage EPSs and clarified certain definitions within the single voltage EPS test procedure. See 76 FR 31750 (June 1, 2011)

DOE initiated its current rulemaking effort for these products by issuing the Energy Conservation Standards Rulemaking Framework Document for Battery Chargers and External Power Supplies (the framework document), which explained, among other things, the issues, analyses, and process DOE would follow in developing potential standards for non-Class A EPSs and amended standards for Class A EPSs. See *http://www.regulations.gov/#!documentDetail;D=EERE-2008-BT-STD-0005-0005*. 74 FR 26816 (June 4, 2009). DOE also published a notice of proposed determination regarding the setting of standards for non-Class A EPSs. 74 FR 56928 (November 3, 2009). These notices were followed by a final determination published on May 14, 2010, 75 FR 27170, which concluded that energy conservation standards for non-Class A EPSs appeared to be technologically feasible and economically justified, and would be likely to result in significant energy savings. Consequently, DOE decided to include non-Class A EPSs in the present energy conservation standards rulemaking for battery chargers and EPSs.[13]

On September 15, 2010, having considered comments from interested parties, gathered additional information, and performed preliminary analyses for the purpose of developing potential amended energy conservation standards for Class A EPSs and new energy conservation standards for battery chargers and non-Class A EPSs, DOE announced a public meeting and the availability on its Web site of a preliminary technical support document (preliminary TSD). 75 FR 56021. The preliminary TSD discussed the comments DOE had received in response to the framework document and described the actions DOE had taken up to this point, the analytical framework DOE was using, and the content and results of DOE's preliminary analyses. *Id.* at 56023, 56024. DOE convened the public meeting to discuss and receive comments on: (1) The product classes DOE analyzed, (2) the analytical framework, models, and tools that DOE was using to evaluate potential standards, (3) the results of the preliminary analyses performed by DOE, (4) potential standard levels that DOE might consider, and (5) other issues participants believed were relevant to the rulemaking. *Id.* at 56021, 56024. DOE also invited written comments on these matters. The public meeting took place on October 13, 2010. Many interested parties participated by submitting written comments.

DOE published a notice of proposed rulemaking (NOPR) on March 27, 2012. 77 FR 18478. Shortly after, DOE also published on its Web site the complete TSD for the proposed rule, which incorporated the complete analyses DOE conducted and technical documentation for each analysis. The NOPR TSD included the LCC spreadsheet, the national impact analysis spreadsheet, and the manufacturer impact analysis (MIA) spreadsheet—all of which are available in the docket for this rulemaking. In the March 2012 NOPR, in addition to proposing potential standards for battery chargers, DOE

[12] To help ensure that the standards Congress set were not applied in an overly broad fashion, DOE applied the statutory exclusion not only to those EPSs that require FDA listing and approval but also to any EPS that provides power to a medical device.

[13] See *http://www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/23.*

proposed amended energy conservation standards for EPSs as follows:

Table II-2 Proposed Energy Conservation Standards for Direct Operation External Power Supplies

AC-DC, Basic-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 * P_{out} + 0.16$	≤ 0.100
1 W < $P_{out} \leq 49$ W	$\geq 0.071 * \ln(P_{out}) - 0.0014 * P_{out} + 0.67$	≤ 0.100
49 W < $P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
AC-DC, Low-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 * P_{out} + 0.087$	≤ 0.100
1 W < $P_{out} \leq 49$ W	$\geq 0.0834 * \ln(P_{out}) - 0.0014 * P_{out} + 0.609$	≤ 0.100
49 W < $P_{out} \leq 250$ W	≥ 0.870	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
AC-AC, Basic-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 * P_{out} + 0.16$	≤ 0.210
1 W < $P_{out} \leq 49$ W	$\geq 0.071 * \ln(P_{out}) - 0.0014 * P_{out} + 0.67$	≤ 0.210
49 W < $P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500
AC-AC, Low-voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 * P_{out} + 0.087$	≤ 0.210
1 W < $P_{out} \leq 49$ W	$\geq 0.0834 * \ln(P_{out}) - 0.0014 * P_{out} + 0.609$	≤ 0.210

49 W < P_{out} ≤ 250 W	≥ 0.870	≤ 0.210
P_{out} > 250 W	≥ 0.875	≤ 0.500
Multiple-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
P_{out} ≤ 1 W	≥ 0.497 × P_{out} + 0.067	≤ 0.300
1 W < P_{out} ≤ 49 W	≥ 0.075 × ln (P_{out}) + 0.561	≤ 0.300
P_{out} > 49 W	≥ 0.860	≤ 0.300

In the March 2012 NOPR, DOE identified 36 specific issues related to battery chargers and EPSs on which it was particularly interested in receiving comments. *Id.* at 18642–18644. DOE also sought comments and data that would allow DOE to further bring clarity to the issues surrounding battery chargers and EPSs, and determine how the issues discussed in the March 2012 NOPR could be adequately addressed. DOE also held a public meeting in Washington, DC, on May 2, 2012, to solicit comment and information from the public relevant to the proposed rule. Finally, DOE received many written comments on these and other issues in response to the March 2012 NOPR. All commenters, along with their corresponding abbreviations and organization type, are listed in Table II–3. In today's notice, DOE summarizes and addresses the issues these commenters raised that relate to EPSs. The March 2012 NOPR included additional, detailed background information on the history of this rulemaking. *See id.* at 18493– 18495.

TABLE II–3—LIST OF COMMENTERS

Organization	Abbreviation	Organization type
ARRIS Group, Inc.	ARRIS Group	Manufacturer.
ASAP, ASE, ACEEE, CFA, NEEP, and NEEA	ASAP, *et al.*	Energy Efficiency Advocates.
Association of Home Appliance Manufacturers	AHAM	Industry Trade Association.
Brother International Corporation	Brother International	Manufacturer.
California Energy Commission	California Energy Commission	State Entity.
California Investor-Owned Utilities	CA IOUs	Utilities.
Cobra Electronics Corporation	Cobra Electronics	Manufacturer.
Consumer Electronics Association	CEA	Industry Trade Association.
Delta-Q Technologies Corp.	Delta-Q Technologies	Manufacturer.
Dual-Lite, a Division of Hubbell Lighting, Inc.	Dual-Lite	Manufacturer.
Duracell	Duracell	Manufacturer.
Eastman Kodak Company	Eastman Kodak	Manufacturer.
Flextronics Power	Flextronics	Manufacturer.
GE Healthcare	GE Healthcare	Manufacturer.
Information Technology Industry Council	ITI	Industry Trade Association.
Jerome Industries, a subsidiary of Astrodyne	Jerome Industries	Manufacturer.
Korean Agency for Technology and Standards	Republic of Korea	Foreign Government.
Logitech Inc.	Logitech	Manufacturer.
Microsoft Corporation	Microsoft	Manufacturer.
Motorola Mobility, Inc.	Motorola Mobility	Manufacturer.
National Electrical Manufacturers Association	NEMA	Industry Trade Association.
Natural Resources Defense Council	NRDC	Energy Efficiency Advocate.
Nintendo of America Inc.	Nintendo of America	Manufacturer.
Nokia Inc.	Nokia	Manufacturer.
Northeast Energy Efficiency Partnerships	NEEP	Energy Efficiency Advocate.
Northwest Energy Efficiency Alliance and the Northwest Power and Conservation Council.	NEEA and NPCC	Energy Efficiency Advocates.
NRDC, ACEEE, ASAP, CFA, Earthjustice, MEEA, NCLC, NEEA, NEEP, NPCC, Sierra Club, SEEA, SWEEP.	NRDC, *et al.*	Energy Efficiency Advocates.
Panasonic Corporation of North America	Panasonic	Manufacturer.
PG&E and SDG&E	PG&E and SDG&E	Utilities.
Philips Electronics	Philips	Manufacturer.
Plantronics	Plantronics	Manufacturer.
Power Sources Manufacturers Association	PSMA	Industry Trade Association.
Power Tool Institute, Inc.	PTI	Industry Trade Association.
Salcomp Plc	Salcomp	Manufacturer.
Schneider Electric	Schneider Electric	Manufacturer.
Security Industry Association	SIA	Industry Trade Association.
Telecommunications Industry Association	TIA	Industry Trade Association.

TABLE II–3—LIST OF COMMENTERS—Continued

Organization	Abbreviation	Organization type
Wahl Clipper Corporation	Wahl Clipper	Manufacturer.

III. General Discussion

A. Compliance Date

The compliance date is the date when a new standard becomes operative, i.e., the date by which EPS manufacturers must manufacture products that comply with the standard. EISA 2007 directed DOE to complete a rulemaking to amend the Class A EPS standards by July 1, 2011, with compliance required by July 1, 2013, i.e., giving manufacturers a two-year lead time to satisfy those standards. (42 U.S.C. 6295(u)(3)(D)(i)) There are no similar requirements for non-Class A EPSs. DOE used a compliance date of 2013 in the analysis it prepared for its March 2012 NOPR. As a result, some interested parties assumed in their comments to DOE that the compliance date would be July 1, 2013.

Many parties submitted comments on the duration of the compliance period for EPS standards. Nokia and Plantronics requested 18 to 24 months; AHAM, CEA, Eastman Kodak, Flextronics, ITI, Microsoft, and Salcomp requested two years; Panasonic requested a minimum of two years and preferably three years; Nintendo of America requested four years; and Motorola Mobility requested at least five years. These commenters cited the need to make engineering design changes, conduct reliability evaluations, and obtain regulatory approvals for safety, EMC, and other global standards. (Nokia, No. 132 at p. 2; Plantronics, No. 156 at p. 1; AHAM, No. 124 at p. 5; CEA, No. 106 at p. 6; Eastman Kodak, No. 125 at p. 1; Flextronics, No. 145 at p. 1; ITI, No. 131 at p. 6; Microsoft, No. 110 at p. 3; Salcomp, No. 73 at p. 2; Panasonic, No. 120 at p. 5; Nintendo of America, No. 135 at p. 1; Motorola Mobility, No. 121 at p. 2) NEMA also cautioned that the broad scope and severe limits in the proposed rule would force the withdrawal of systems from the marketplace until testing is concluded and threaten the availability of certain consumer products if insufficient lead time is provided. (NEMA, No. 134 at p. 2) CEA and Panasonic later submitted supplemental comments in response to DOE's March 2013 Request for Information requesting that DOE require compliance in 2017, to harmonize with the standards the European Union has proposed adopting. (CEA, No. 208 at p. 4; Panasonic, No. 210 at p. 2)

Consistent with the two-year lead time provided in EPCA, and in light of the passing of the statutorily-prescribed 2013 effective date, DOE will provide manufacturers with a lead-time of the same duration as prescribed by statute to comply with the new and amended standards set forth in today's final rule. EISA 2007 directed DOE to publish a final rule for EPSs by July 1, 2011 and further stipulated that any amended standards would apply to products manufactured on or after July 1, 2013, two years later. (42 U.S.C. 6295(u)) In DOE's view, Congress created this two-year interval to ensure that manufacturers would have sufficient time to meet any new and amended standards that DOE may set for EPSs. In effect, DOE is preserving the original compliance period length contained in EISA 2007 and ensuring that manufacturers will have sufficient time to transition to the new and amended standards.

B. Product Classes and Scope of Coverage

1. General

When evaluating and establishing energy conservation standards, DOE may divide covered products into product classes by the type of energy used or by capacity or other performance-related features that would justify a different standard. In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE determines are appropriate. See 42 U.S.C. 6295(q) (outlining the criteria by which DOE may set different standards for a product). EPS product classes are discussed in section IV.A.2.

An "external power supply" is an external power supply circuit that is used to convert household electric current into DC current or lower-voltage AC current to operate a consumer product. (42 U.S.C. 6291(36)(A)) EPCA, as amended by EISA 2007, also prescribes the criteria for a subcategory of EPSs—those classified as Class A EPSs (or in context, "Class A"). Under 42 U.S.C. 6291(36)(C)(i), a Class A EPS is a device that:

1. Is designed to convert line voltage AC input into lower voltage AC or DC output;
2. is able to convert to only one AC or DC output voltage at a time;
3. is sold with, or intended to be used with, a separate end-use product that constitutes the primary load;
4. is contained in a separate physical enclosure from the end-use product;
5. is connected to the end-use product via a removable or hard-wired male/female electrical connection, cable, cord, or other wiring; and
6. has nameplate output power that is less than or equal to 250 watts.

The Class A definition excludes any device that either (a) requires Federal Food and Drug Administration listing and approval as a medical device in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)) or (b) powers the charger of a detachable battery pack or charges the battery of a product that is fully or primarily motor operated. See 42 U.S.C. 6291(36)(C)(ii).

Based on DOE's examination of product information, all EPSs appear to share four of the six criteria under the Class A definition in that all are:

- Designed to convert line voltage AC input into lower voltage AC or DC output;
- sold with, or intended to be used with, a separate end-use product that constitutes the primary load;
- contained in a separate physical enclosure from the end-use product; and
- connected to the end-use product via a removable or hard-wired male/female electrical connection, cable, cord, or other wiring.

Examples of devices that fall outside of Class A (in context, "non-Class A") include EPSs that can convert power to more than one output voltage at a time (multiple voltage), EPSs that have nameplate output power exceeding 250 watts (high-power), EPSs used to power medical devices, and EPSs that provide power to the battery chargers of motorized *a*pplications and *d*etachable *b*attery packs (MADB). After examining the potential for energy savings that could result from standards for non-Class A devices, DOE concluded that standards for these devices would be likely to result in significant energy savings and be technologically feasible and economically justified. 75 FR 27170 (May 14, 2010). With today's notice, DOE is amending the current standards for Class A EPSs and adopting new

standards for multiple-voltage and high-power EPSs.

NEMA commented in response to the NOPR that combining battery chargers and EPSs into a single rulemaking created burden on manufacturers in terms of being able to process the standards proposed in the NOPR. NEMA recommended that DOE delay the announcement of new and amended standards for EPSs and begin a new rulemaking process dedicated solely to EPSs after publishing a final rule for battery chargers. According to NEMA, EISA 2007 allows DOE to opt out of amending standards at this time if those standards are not warranted and instead revisit the possibility of amending EPS standards as part of a second rulemaking cycle. (NEMA, No. 134 at p. 6)

With respect to battery chargers, DOE issued a Request for Information (RFI) on March 26, 2013, in which DOE sought additional information. (78 FR 18253) The RFI sought, among other things, information on battery chargers that manufacturers had certified as compliant with the California Energy Commission (CEC) standards that became effective on February 1, 2013. The notice also offered commenters the opportunity to raise for comment any other issues relevant to the proposal.

Several efficiency advocates submitted comments in response to DOE's RFI, requesting that DOE split the combined battery charger and EPS rulemaking into two separate rulemakings and issue EPS standards as soon as possible. (NRDC, *et al.*, No. 209 at p. 2; CA IOUs, No. 197 at p. 9; California Energy Commission, No. 199 at p. 14; NEEA and NPCC, No. 200 at p. 2) These commenters gave three reasons for quickly finalizing the EPS rule: (1) The significant energy and economic savings expected to result from the EPS standard, (2) the need to move quickly to finalize standards before the underlying technical data become outdated, and (3) the statutory deadline of July 1, 2011 for publishing the EPS final rule. In response to DOE's March 2013 Request for Information, Dual-Lite, a division of Hubbell Lighting, commented that it "challenges the DOE to adopt a bias towards action in rulemakings, whereby initial rules are performed with a cant towards getting a more modest rule out the door in a timely manner, versus chasing every 0.01 watt of potential savings . . . and delaying actual energy savings by months or years." (Dual-Lite, No. 189 at p. 3)

As explained above, this rulemaking initially addressed both battery chargers and EPSs. After proposing standards for both product types in March 2012, and giving careful consideration to the complexity of the issues related to the setting of standards for battery chargers, DOE has decided to adopt energy conservation standards for EPSs while weighing for further consideration the promulgation of energy conservation standards for battery chargers at a later date. The battery charger rulemaking has been complicated by a number of factors, including the setting of standards by the CEC, which other states have chosen to follow.[14] Because the California standards have already become effective, manufacturers are already required to meet that battery charger standard. DOE has previously indicated that the facts before it did not indicate that it would be likely manufacturers would continue to create separate products for California and the rest of the country. See 77 FR at 18502. The likelihood of this split-approach occurring is even less likely, given that other states have adopted the California standards. As a result, DOE believes that manufacturers are already making efforts to meet the levels set by California. To avoid unnecessary disruptions to the market, provide some level of consistency and stability to affected entities, and to further evaluate the impacts associated with the California-based standards, DOE is deferring the setting of battery charger standards at this time. Consequently, today's notice focuses solely on the standards that are being adopted today for EPSs, along with the detailed product classes that will apply. For further detail, see the March 2013 Request for Information.

2. Definition of Consumer Product

As noted above, the term "external power supply" refers to an external power supply circuit that is used to convert household electric current into DC current or lower-voltage AC current to operate a consumer product.

DOE received comments from a number of stakeholders seeking clarification on the definition of a consumer product. Schneider Electric commented that the definition of consumer product is "virtually unbounded" and "provides no definitive methods to distinguish commercial or industrial products from consumer products." (Schneider Electric, No. 119 at p. 2) ITI commented that a more narrow definition of a consumer product is needed to determine which state regulations are preempted by federal standards. (ITI, No. 131 at p. 2) NEMA commented that the FAQ on the DOE Web site is insufficient to resolve its members' questions. (NEMA, No. 134 at p. 2) NEMA further sought clarification on whether EPSs that power building system components are within the scope of this rulemaking. According to NEMA, such EPSs typically are permanently installed in electrical rooms near the electrical entrance to the building and power such things as communication links, central processors for building or lighting management systems, and motorized shades. (NEMA, No. 134 at pp. 6–7) These stakeholders suggested ways that DOE could clarify the definition of a consumer product:

- Adopt the ENERGY STAR battery charger definition.
- Limit the scope to products marketed as compliant with the FCC's Class B emissions limits.
- Define consumer products as "pluggable Type A Equipment (as defined by IEC 60950–1), with an input rating of less than or equal to 16A."

Lutron Electronics commented that it does not believe that the EPSs that power components of the lighting control systems and window shading systems it manufactures are within the scope of the EPS rulemaking because EPSs that meet the special requirements of such applications and meet the proposed standards are not commercially available. (Lutron Electronics, No. 141 at p. 2) DOE also received comments from NEMA and Philips regarding how DOE would treat illuminated exit signs and egress lighting. (NEMA, No. 134 at p. 6; Philips, No. 128 at p. 2)

EPCA defines a consumer product as any article of a type that consumes or is designed to consume energy and which, to any significant extent, is distributed in commerce for personal use or consumption by individuals. See 42 U.S.C. 6291(1). Manufacturers are advised to use this definition (in conjunction with the EPS definition) to determine whether a given device shall be subject to EPS standards. Additional guidance is contained in the FAQ document that NEMA referred to, which can be downloaded from DOE's Web site.[15]

Consistent with the statutory language and guidance noted above, DOE notes that Congress treated EPSs, along with illuminated exit signs, as consumer products. See 42 U.S.C. 6295(u) and (w) (provisions related to requirements for EPSs and illuminated exit signs, both of

[14] Oregon has adopted the California standards; Washington, Connecticut and New Jersey are considering doing the same.

[15] *http://www1.eere.energy.gov/buildings/appliance_standards/pdfs/cce_faq.pdf.*

which are located in Part A of EPCA, which addresses residential consumer products). In light of this treatment, by statute, EPSs are considered consumer products under EPCA. Accordingly, DOE is treating these products in a manner consistent with the framework established by Congress.

3. Power Supplies for Solid State Lighting

NEMA and Philips commented that power supplies for solid state lighting (SSL) should not be included in the scope of this rulemaking. (NEMA, No. 134 at pp. 3–7; Philips, No. 128 at p. 2) They offered the following arguments against the inclusion of SSL power supplies:

- SSL is often used in commercial applications, and therefore should not be considered a consumer product;
- SSL power supplies are considered a part of the system as a whole and typically tested as such;
- SSL power supplies perform other functions in addition to power conversion, such as dimming;
- SSL is an emerging technology and increasing efficiency could lead to costs that are prohibitive to most consumers; and
- Regulating components of SSL could contradict DOE's other efforts, which include promoting the adoption of SSL.

DOE notes that Congress prescribed the criteria for an EPS to meet in order to be considered a covered product. A device meeting those criteria is an EPS under the statute and subject to the applicable EPS standards. DOE has no authority to alter these statutorily-prescribed criteria.

Further, all Class A EPSs are subject to the current Class A EPS standards, and those that are direct operation EPSs will be subject to the amended EPS standards being adopted today. The fact that a given type of product, such as SSL products, is often used in commercial applications does not mean that it is not a consumer product, as explained above. DOE recognizes that many EPSs are considered an integral part of the consumer products they power and may be tested as such; however, this does not obviate the need to ensure that the EPS also meets applicable EPS standards. DOE has determined that there are no technical differences between the EPSs that power certain SSL (including LED) products and those that are used with other end-use applications. And as DOE indicated in its proposal, although it did not initially include these devices as part of its NOPR analysis, DOE indicated that it may consider revising this aspect of its analysis. 77 FR at 18503. Therefore, DOE believes that subjecting SSL EPSs to EPS standards will not adversely impact SSL consumers, since these devices should be able to satisfy the standards. DOE notes that following this approach is also consistent with DOE's other efforts, including those to promote the broader adoption of SSL technologies.

4. Medical Devices

As explained above, EPSs for medical devices are not subject to the current standards created by Congress in December 2007. In its May 2010 determination, DOE initially determined that standards for EPSs used to power medical devices were warranted because they would result in significant energy savings while being technologically feasible and economically justified. As a result, in the March 2012 NOPR, DOE proposed standards for these devices.

DOE subsequently received comments from GE Healthcare and Jerome Industries, which manufactures power supplies for medical devices. These commenters gave several reasons not to apply standards to these products. The commenters noted that the design, manufacture, maintenance, and post-market monitoring of medical devices is highly regulated by the U.S. FDA, and EPS standards would only add to this already quite substantial regulatory burden. They also commented that there are a large number of individual medical device models, each of which must be tested along with its component EPS to ensure compliance with applicable standards; redesign of the EPS to meet DOE standards would require that all of these models be retested and reapproved, at a significant per-unit cost, especially for those devices that are produced in limited quantities. Jerome Industries also expressed concern that the proposed EPS standards are inconsistent with the reliability and safety requirements incumbent on some medical devices, *i.e.,* asserting that an EPS cannot be engineered to meet the proposed standards and these other requirements. Lastly, Jerome Industries noted that medical EPSs are exempt from EPS standards in other jurisdictions, including Europe, Australia, New Zealand, and California. (GE Healthcare, No. 142 at p. 2; Jerome Industries, No. 191 at pp. 1–2)

Given these concerns, DOE has reevaluated its proposal to set energy conservation standards for medical device EPSs. While DOE believes, based on available data, that standards for these devices may result in energy savings, DOE also wishes to avoid any action that could potentially impact reliability and safety. In the absence of sufficient data on this issue, and consistent with DOE's obligation to consider such adverse impacts when identifying and screening design options for improving the efficiency of a product, DOE has decided to refrain from setting standards for medical EPSs at this time. See 42 U.S.C. 6295(o)(2)(b)(i)(VII). See also 10 CFR part 430, subpart C, appendix A, (4)(a)(4) and (5)(b)(4) (collectively setting out DOE's policy in evaluating potential energy conservation standards for a product).

5. Security and Life Safety Equipment

The Security Industry Association sought confirmation that "security or life safety alarms or surveillance systems" would continue to be excluded from the no-load power requirements that were first established in EISA 2007. (SIA, No. 115 at pp. 1–2) See also 42 U.S.C. 6295(u)(3)(E). This exclusion applies only to the no-load mode standard established in EISA 2007 for Class A EPSs. Consistent with this temporary exemption, DOE is not requiring these devices to meet a no-load mode requirement. Therefore, life safety and security system EPSs will, until the statutorily-prescribed sunset date of July 1, 2017, not be required to meet a no-load standard. At the appropriate time, DOE will re-examine this exemption and may opt to prescribe no-load standards for these products in the future.

6. Service Parts and Spare Parts

Several commenters requested a temporary exemption from the standards being finalized today for service part and spare part EPSs. (CEA, No. 106 at p. 7; Eastman Kodak, No. 125 at p. 2; ITI, No. 131 at p. 9; Motorola Mobility, No. 121 at p. 11; Nintendo of America, No. 135 at p. 2) Panasonic commented that "a seven-year exemption is necessary for manufacturers to meet their legal and customer service obligations to stock and supply spare parts for sale, product servicing, and warranty claims for existing products." (Panasonic, No. 120 at p. 6) Panasonic later requested a 9-year exemption, in response to DOE's March 2013 Request for Information. (Panasonic, No. 210 at p. 2) Brother International cited the added cost and unnecessary electronic waste that would result from having to stockpile a sufficient quantity of legacy EPSs to meet future needs for service or spare parts. (Brother International, No. 111 at p. 2)

EPCA exempts Class A EPSs from meeting the statutorily prescribed standards if the devices are manufactured before July 1, 2015, and are made available by the manufacturer as service parts or spare parts for end-use consumer products that were manufactured prior to the end of the compliance period (July 1, 2008). (42 U.S.C. 6295(u)(3)(B)) Congress created this limited (and temporary) exemption as part of a broad range of amendments under EISA 2007. The provision does not grant DOE with the authority to expand or extend the length of this exemption and Congress did not grant DOE with the general authority to exempt any already covered product from the requirements set by Congress. Accordingly, DOE cannot grant the relief sought by these commenters.

C. Technological Feasibility

Energy conservation standards promulgated by DOE must be technologically feasible. This section addresses the manner in which DOE assessed the technological feasibility of the new and amended standards being adopted today.

1. General

In each standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(i).

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, or service; (2) adverse impacts on product utility or availability; and (3) adverse impacts on health or safety. Section IV.B of this notice discusses the results of the screening analysis for EPSs, particularly the designs DOE considered, those it screened out, and those that are the basis for the trial standard levels (TSLs) analyzed in this rulemaking. For further detail, see chapter 4 of the technical support document (TSD), which accompanies this final rule and can be found in the docket on regulations.gov.

2. Maximum Technologically Feasible Levels

When proposing an amended standard for a type or class of covered product, DOE must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible ("max-tech") improvements in energy efficiency for EPSs using the design parameters for the most efficient products available on the market or in working prototypes. (See chapter 5 of the final rule TSD.) The max-tech levels that DOE determined for this rulemaking are described in section IV.C of this final rule.

D. Energy Savings

1. Determination of Savings

For each TSL, DOE projected energy savings from the products that are the subject of this rulemaking purchased in the 30-year period that begins in the year of compliance with new and amended standards (2015–2044). The savings are measured over the entire lifetime of products purchased in the 30-year period.[16] DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the base case. The base case represents a projection of energy consumption in the absence of new and amended mandatory efficiency standards, and considers market forces and policies that affect demand for more efficient products.

DOE used its national impact analysis (NIA) spreadsheet model to estimate energy savings from new and amended standards for the products that are the subject of this rulemaking. The NIA spreadsheet model (described in section IV.H of this notice) calculates energy savings in site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of the savings in the energy that is used to generate and transmit the site electricity. To calculate this quantity, DOE derives annual conversion factors from the model used to prepare the Energy Information Administration's (EIA) *Annual Energy Outlook (AEO).*

DOE has also begun to estimate full-fuel-cycle energy savings. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (August 17, 2012). The full-fuel-cycle (FFC) metric includes the energy consumed in extracting, processing, and transporting primary fuels, and thus presents a more complete picture of the impacts of energy efficiency standards. For this final rule, DOE did not include the FFC in the NIA. However, DOE developed a sensitivity analysis that estimates these additional impacts from production activities. DOE's approach is based on calculation of an FFC multiplier for each of the energy types used by covered products.

2. Significance of Savings

As noted above, 42 U.S.C. 6295(o)(3)(B) prevents DOE from adopting a standard for a covered product unless such standard would result in "significant" energy savings. Although the term "significant" is not defined in the Act, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *Herrington,* 768 F.2d 1355, 1373 (D.C. Cir. 1985), indicated that Congress intended "significant" energy savings in this context to be savings that were not "genuinely trivial." The energy savings for all of the TSLs considered in this rulemaking (presented in section V.B.3) are nontrivial, and, therefore, DOE considers them "significant" within the meaning of section 325 of EPCA.

E. Economic Justification

1. Specific Criteria

EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)) This section discusses how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a new and amended standard on manufacturers, DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term

[16] In the past DOE presented energy savings results for only the 30-year period that begins in the year of compliance. In the calculation of economic impacts, however, DOE considered operating cost savings measured over the entire lifetime of products purchased in the 30-year period. DOE has chosen to modify its presentation of national energy savings to be consistent with the approach used for its national economic analysis.

assessment over a 30-year period. The industry-wide impacts analyzed include industry net present value (INPV), which values the industry on the basis of expected future cash flows; cash flows by year; changes in revenue and income; and other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in life-cycle cost (LCC) and payback period (PBP) associated with new and amended standards. The LCC, which is specified separately in EPCA as one of the seven factors to be considered in determining the economic justification for a new and amended standard, 42 U.S.C. 6295(o)(2)(B)(i)(II), is discussed in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the economic impacts applicable to a particular rulemaking.

b. Life-Cycle Costs

The LCC is the sum of the purchase price of a product (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC savings for the considered efficiency levels are calculated relative to a base case that reflects projected market trends in the absence of new and amended standards. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and consumer discount rates. For its analysis, DOE assumes that consumers will purchase the considered products in the first year of compliance with new and amended standards.

To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value. DOE identifies the percentage of consumers estimated to receive LCC savings or experience an LCC increase, in addition to the average LCC savings associated with a particular standard level. DOE also evaluates the LCC impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a national standard.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for imposing an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section IV.H, DOE uses the NIA spreadsheet to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing classes of products, and in evaluating design options and the impact of potential standard levels, DOE evaluates standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) DOE received no comments that EPS standards would increase their size and reduce their convenience nor have any other significant adverse impacts on consumer utility. Thus, DOE believes that the standards adopted in today's final rule will not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of a standard. (42 U.S.C. 6295(o)(2)(B)(i)(V) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE transmitted a copy of its proposed rule to the Attorney General with a request that the Department of Justice (DOJ) provide its determination on this issue. DOJ did not file any comments or determination with DOE on the proposed rule.

f. Need for National Energy Conservation

The energy savings from new and amended standards are likely to provide improvements to the security and reliability of the nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the nation's needed power generation capacity.

The new and amended standards also are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases associated with energy production. DOE reports the emissions impacts from today's standards and from each TSL it considered in section V.B.6 of this notice. DOE also reports estimates of the economic value of emissions reductions resulting from the considered TSLs.

g. Other Factors

EPCA allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII))

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential new and amended energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in sections IV.F.15 and V.B.1.c of this final rule.

IV. Methodology and Discussion

A. Market and Technology Assessment

For the market and technology assessment, DOE develops information

that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, and market characteristics. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this rulemaking include product classes and manufacturers; quantities and types of products sold and offered for sale; retail market trends; regulatory and non-regulatory programs; and technologies or design options that could improve the energy efficiency of the products under examination. See chapter 3 of the TSD for further detail.

1. Market Assessment

To characterize the market for EPSs, DOE gathered information on the products that use them. DOE refers to these products as end-use consumer products or EPS "applications." This method was chosen for two reasons. First, EPSs are nearly always bundled with or otherwise intended to be used with a given application; therefore, the demand for applications drives the demand for EPSs. Second, because most EPSs are not stand-alone products, their shipments, lifetimes, usage profiles, and power requirements are all determined by the associated application.

DOE analyzed the products offered by online and brick-and-mortar retail outlets to determine which applications use EPSs and which EPS technologies are most prevalent. The list of applications analyzed and a full explanation of the market assessment methodology can be found in chapter 3 of the TSD.

While DOE identified the majority of EPS applications, some may not have been included in the NOPR analysis. This is due in part because the EPS market is dynamic and constantly evolving. As a result some applications that use EPSs were not found because they either made up an insignificant market share or were introduced to the market after the NOPR analysis was conducted. The EPSs for any other applications not explicitly analyzed in the market assessment will still be subject to the standards announced in today's notice as long as they meet the definition of a covered product outlined in the previous section. That is, DOE's omission of any particular EPS application from its analysis is not by itself an indication that the EPSs that power that application are not subject to EPS standards.

DOE relied on published market research to estimate base-year shipments for all applications. DOE estimated that in 2009 a total of 345 million EPSs were shipped for final sale in the United States.

DOE did not receive any comments on its assumptions for total base year (2009) EPS shipments, but did receive comments on its efficiency distributions. ARRIS Group commented that it is nearly impossible to purchase EPSs at level IV (the current federal standard level) because nearly all products comply with the ENERGY STAR standard (level V); ARRIS Group, however, provided no data in support of this claim.[17] (ARRIS Group, No. 105 at p. 1) To determine the distribution of shipments at different efficiency levels, DOE relied on EPS testing conducted as part of the Engineering Analysis. Of the products DOE tested, 61% were below level V. DOE assumed that half of the EPSs below level V would improve in efficiency up to level V by the beginning of the analysis period in 2015, leaving 30% at level IV and the remaining 70% at level V or higher. When the ENERGY STAR program for EPSs ended in 2010, EPA estimated that over 50% of the market had reached level V efficiency or higher.[18] DOE appreciates ARRIS Group's input on this subject, but has maintained its estimate from the NOPR because it is in line with the available data.

2. Product Classes

When necessary, DOE divides covered products into classes by the type of energy used, the capacity of the product, and any other performance-related feature that justifies different standard levels, such as features affecting consumer utility. (42 U.S.C. 6295(q)) DOE then conducts its analysis and considers establishing or amending standards to provide separate standard levels for each product class.

a. Proposed EPS Product Classes

In the NOPR, DOE proposed dividing EPSs into those that can directly operate an end-use consumer product and those that cannot, termed "direct operation EPSs" and "indirect operation EPSs," respectively. DOE proposed standards only for direct operation EPSs.

There exist both Class A and non-Class A indirect operation EPSs. DOE believes that these two groups of devices are technically equivalent, *i.e.*, there is no difference in performance-related features between the two groups that would justify different standard levels for the two groups. (42 U.S.C. 6295(q)) Because of this technical equivalency, DOE grouped these EPSs into one product class for analysis, product class N.

DOE proposed to divide direct operation EPSs into six product classes. Two of these six product classes were treated as non-Class A EPSs: Product class X for multiple-voltage EPSs (multiple simultaneous output currents) and product class H for high-output power EPSs (nameplate output power > 250 Watts). All other direct operation EPSs were divided among the remaining four product classes (B, C, D, and E) and are largely composed of Class A EPSs.

These classes, however, also contain some non-Class A EPSs, specifically direct operation EPSs for battery charged motorized applications. Medical EPSs were previously included, but have since been removed, as explained in section IV.A.1 above. While these devices are functionally the same as Class A devices, they were excluded from the Class A definition through Congressional action. See 42 U.S.C. 6291(36).

The primary criteria for determining which of these four product classes a given EPS falls into are the type of output current (AC or DC) and the nameplate output voltage (low-voltage or basic-voltage). These are the same parameters used by the former ENERGY STAR program, which DOE used to develop a framework for its EPS analysis. DOE proposed adopting the ENERGY STAR definitions for low-voltage and standard voltage EPSs with minor variations. According to these definitions, if a device has a nameplate output voltage of less than 6 volts and its nameplate output current is greater than or equal to 550 milliamps, DOE considers that device a low-voltage EPS. A product that does not meet the criteria for being a low-voltage EPS is classified as a standard-voltage EPS. DOE proposed to use the term "basic voltage" in place of "standard voltage."

DOE also proposed definitions for AC–DC and AC–AC EPSs. If an EPS converts household electrical current into DC output, DOE classifies that product as an AC–DC EPS. Conversely, a device that converts household electrical current into a lower voltage AC output is an AC–AC EPS. Using these parameters, DOE was able to outline the specific requirements for its

[17] By statute, Class A EPSs be marked with a Roman numeral IV. See 42 U.S.C. 6295(u)(3)(C). Since the enactment of that requirement, EPA adopted the Roman numeral V mark for products that meet the ENERGY STAR criteria (version 2.0). These Roman numerals correspond to higher levels of efficiency—i.e. V denotes a higher level of efficiency than IV.

[18] U.S. Environmental Protection Agency, May 26, 2010, Accessed at *http://www.energystar.gov/ia/partners/prod_development/revisions/downloads/eps_eup_sunset_stakeholder_proposal.pdf?6ec1-54bb*

product classes included in the EPS rulemaking.

The next two subsections summarize comments DOE received on the proposed product classes and explain how DOE has addressed these comments. The subsection that follows contains a list of the product classes and definitions being adopted today.

b. Differentiating Between Direct and Indirect Operation EPSs

An indirect operation EPS is an EPS that cannot power a consumer product (other than a battery charger) without the assistance of a battery. In other words, if an end-use product only functions when drawing power from a battery, the EPS associated with that product is classified as an indirect operation EPS. Because the EPS must first deliver power and charge the battery before the end-use product can function as intended, DOE considers this device an indirect operation EPS and defined a separate product class, N, for all such devices. Conversely, if the battery's charge status does not impact the end-use product's ability to operate as intended, and the end-use product can function using only power from the EPS, DOE considers that device a direct operation EPS.

DOE's initial approach for determining whether a given EPS has direct operation capability involved removing the battery from the application and attempting to operate the application using only power from the EPS. While this approach gave the most definitive EPS classifications, this procedure had the potential to create complications during testing since it frequently requires the removal of integral batteries prior to testing. The removal of such batteries can often require access to internal circuitry via sealed moldings capable of shattering and damaging the application. DOE also considered revising this method to account for removable and integral batteries, but believed it might create an overly burdensome process for manufacturers to follow.

DOE then developed a new method to distinguish between direct and indirect operation EPSs that minimizes both the risk of damage to the application and the complexity associated with the removal of internal batteries. This approach requires manufacturers to determine whether an EPS can operate its end-use product once the associated battery has been fully discharged. Based on its close examination of a variety of products, DOE believes that direct operation EPSs are able to power the application regardless of the state of the battery, while indirect-operation EPSs need to charge the battery before the application can be used as intended. Comparing the time required for an application to operate once power is applied during fully discharged and fully charged battery conditions would provide a reliable indication of whether a given EPS is an indirect or direct operation device. Recording the time for the application to reach its intended functionality is necessary because certain applications, such as smartphones, contain firmware that can delay the EPS from operating the end-use product as expected. If the application takes significantly longer to operate once the battery has been fully discharged, DOE views this EPS as one that indirectly operates the end-use consumer product and classifies it as part of product class N. Using this methodology, one can readily determine whether a given device is a direct or indirect operation EPS. See Chapter 5 and Appendix 3C of the TSD for further details.

DOE received several comments on its proposed method for identifying indirect operation EPSs. Philips suggested that DOE allow manufacturers to submit data showing that their products are rarely powered directly from the AC mains despite being designed with such capability and asked that the EPSs used with these products be classified as indirect operation EPSs. (Philips, No. 128 at pp. 3–4) AHAM and Wahl Clipper requested that DOE explicitly define what is considered to be a "fully discharged" battery for determining whether a given device is a direct operation EPS. (AHAM, No. 124 at p. 6: Wahl Clipper, No. 153 at p. 2)

The method for determining whether a device is an indirect operation EPS was developed to separate EPSs into direct operation product classes and the indirect operation product class N, with the emphasis specifically on MADB products. It was developed based on the technical capabilities of the EPS and battery charging systems. Any product's classification determination must be based on the observable technical characteristics of that product. The method evaluates whether the EPS can power the product when the battery is depleted to the point that the battery can no longer operate the end-use consumer product as it was intended to be used. DOE considers this point to be when a battery is "fully discharged."

NRDC commented that DOE's proposed method for determining whether a given device is an indirect operation EPS "incorrectly captures products, such as mobile, smart phones and MP3 players, that have firmware delays on [detection of a] dead battery, but are otherwise capable of operating without the battery." (NRDC, No. 114 at p. 15) NRDC proposed an alternative method that first checks whether the end-use consumer product has a removable battery, similar to the first approach considered by DOE in evaluating whether a particular device is an indirect operation EPS. If the device to which the EPS connects has a removable battery, NRDC suggested removing the battery, connecting the EPS, and attempting to use the product as it was intended. If it operates, NRDC believes it should be considered a direct operation EPS, but if it does not it should be considered an indirect operation EPS. If the battery in the end-use product is not capable of being removed, NRDC suggested using DOE's proposed method but with one modification. Rather than use the five second delay period DOE proposed in the NOPR, NRDC suggested that the delay period be extended to a longer period of time closer to five minutes to "give enough time for firmware functions to complete and avoid any temptation to game the system by introducing artificial delays." (NRDC, No. 114 at p. 15)

Based on the stakeholder comments, DOE has chosen to partially adopt NRDC's proposed method for determining indirect operation with the exception that the determination delay remains five seconds in all cases. DOE closely examined the operational behavior of several smart phones, beard trimmers, and shavers in developing the indirect operation determination method it proposed in the March 2012 NOPR. Based on its analysis, DOE believes that five seconds is an acceptable tolerance for the indirect operation determination method because there was a clear dividing point among the test data that reflected the ability of the battery to operate the end-use products based on the operating time. See Appendix 3C for the full test results from the indirect operation determination. During charging, batteries initially enter a bulk charge mode where a float voltage, or fast-charge voltage, is applied to the battery and the initial charge current is high compared to the average charging current throughout the duration of the charge cycle. DOE believes that this initial cycle could be enough to operate the end-use consumer product after a short period of time, but it does not change the fact that the product is still drawing power from the battery rather than drawing power directly from the EPS itself. No product DOE examined that met the indirect operation criteria

under the determination method came close to operating near the five-second buffer. Instead, the indirect operation EPSs took as little as three times longer (15 seconds) to operate after being discharged and much longer in several cases (85 seconds). DOE believes the 5-second buffer accurately distinguishes between indirect and direct operation EPSs. As NRDC did not provide any data supporting its view that a 5-minute delay was necessary, DOE sees no reason to modify its proposed method in the manner suggested by NRDC.

Regarding NRDC's contention that a longer delay would reduce the risk of gaming, DOE will continue to monitor the operation of these products as part of its periodic review of the test procedures required under 42 U.S.C. 6293. Should DOE discover any anomalies suggesting a manufacturer is circumventing the applicable standards, DOE will make the necessary adjustments to prevent this from occurring.

As part of today's final rule, DOE is combining its proposed methods for determining indirect operation into a single method. DOE previously considered such a hybrid approach, but initially believed the testing might become too burdensome for manufacturers. In light of the comments submitted by interested parties, however, DOE believes the hybrid approach will reduce the complexity involved in examining consumer products that contain a removable battery. There may also be side benefits, outside of identifying whether a device is an indirect or direct operation EPS, including reducing possible ambiguity with the test procedure. See appendix 3C to the TSD for the determination method for indirect operation EPSs.

c. Multiple-Voltage

A multiple-voltage EPS is defined as "an external power supply that is designed to convert line voltage AC input into *more than one simultaneous lower-voltage output.*" See 10 CFR Part 430 Subpart B Appendix Z. Direct operation EPSs that meet this definition are considered multiple-voltage EPSs and will be evaluated using the multiple-voltage EPS test procedure. These products must comply with the new standards being adopted today for multiple-voltage EPSs. An EPS cannot be in more than one product class, so such an EPS need not also comply with the standards being adopted today for product classes B, C, D, E, or H.

In response to the NOPR regarding multiple-voltage EPSs, Cobra Electronics commented that an EPS with multiple simultaneous outputs but only one output voltage would be considered both a multiple-voltage EPS and a Class A EPS and, thus, in its view, would have to be tested according to DOE's multiple-voltage and single-voltage EPS test procedures. (Cobra Electronics, No. 130 at p. 3)

Cobra correctly deduced that an EPS with multiple simultaneous outputs, but only one output voltage could be treated either as a multiple-voltage EPS or a Class A EPS. The term "class A external power supply" means a device that, among other things, is able to convert to *only one AC or DC output voltage at a time.* See 42 U.S.C. 6291(36)(C)(i). As such, an EPS of this type must meet the current standards for Class A EPSs prescribed by Congress in EISA 2007. DOE notes, however, that the new standards being adopted today for multiple-voltage EPSs are more stringent than the current Class A standards. Therefore, any EPS that is tested and shown to comply with the new multiple-voltage EPS standards will be presumed to also comply with the Class A EPS standards prescribed by Congress in EISA 2007.

d. Low-Voltage, High-Current EPSs

PTI supported DOE's efforts to discern which MADB products should be regulated as EPSs and which should be treated as part of a battery charger. According to PTI, the inclusion of product class N "fulfills one of PTI's longstanding concerns that components of battery chargers and battery chargers themselves should not both be regulated, as this 'double indemnity' creates a situation where designs are over-constrained with no incremental consumer benefit." (PTI, No. 133 at p. 3) AHAM and Wahl Clipper, however, submitted identical comments taking issue with the classification of MADB direct operation EPSs and the CSLs DOE considered for these types of products. Instead, both stakeholders suggested DOE split product class C, where their products would fall, into two classes. The first would encompass all direct operation, low-voltage EPSs with a nameplate output voltage rating of 3–6 volts and a current rating of 550–1000 mA. The second class would include all direct operation, low-voltage EPSs with a nameplate output voltage rating of less than 3 volts and a current rating greater than 1000mA. Under the stakeholders' alternative approach, the first group would need to comply with the standard level established in today's amended EPS standards, and the second class would not. These suggestions were based on the stakeholders' shared concern that the standards DOE proposed for product class C were too stringent and beyond the achievable efficiency for low-voltage, high-current EPSs. (Wahl Clipper, No. 153 at p. 2; AHAM, No. 124 at p. 6) Duracell also commented on the proposed standards for direct operation EPSs, expressing concern that EPSs that charge the batteries of motor-operated products such as shavers, epilators, hair clippers, and stick mixers would not be able to meet the proposed minimum active-mode efficiency requirements. (Duracell, No. 109 at pp. 2–3)

The commenters' concern relates to those EPSs that are designed both to charge multiple low-voltage battery cells in parallel and to directly operate an end-use consumer product such as a shaver or beard trimmer. These are often called "cord-cordless" products. The ability to operate an end-use product directly from mains is a distinct consumer utility, as it enables the consumer to use the end-use product when the battery contains insufficient charge. However, having multiple cells generally means that the charging currents are higher and that these types of MADB EPSs will incur significantly greater resistive power losses than other similar direct operation EPSs, as power consumption grows exponentially with an increase in the output current.

Recognizing this technical difference, DOE has introduced an additional criterion for classifying direct operation EPSs that recognizes that certain devices with low-voltage and high-current outputs have a distinct consumer utility, yet would have extreme difficulty meeting the standards being adopted today. Thus, DOE is subdividing product class C, splitting out certain low-voltage, high-current EPSs into a separate product class, product class C–1.[19] Product classes C and C–1 together encompass all direct operation, AC–DC EPSs with nameplate output voltage less than 6 volts and nameplate output current greater than or equal to 550 milliamps ("low-voltage"). Any product in this group that also has nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps and charges the battery of a product that is fully or primarily motor operated is in product class C–1. All others remain in product class C.

Given the differences in these low-voltage, high-current EPSs from the other products falling into product class C, DOE believes there is merit in

[19] In the NOPR analysis, DOE mistakenly placed the EPSs for cord-cordless products in product class B, which contains basic-voltage EPSs. Based on public comments, DOE now recognizes that the EPSs in question are low-voltage EPSs and should have been placed in product class C.

treating them as a separate product class and is currently gathering additional information about this subset of EPSs. In the meantime, DOE is not adopting standards for EPSs in product class C–1 today, but intends to study these products further and may elect to propose efficiency standards for them in a future rulemaking. DOE will issue appropriate notices when undertaking studies to evaluate this class of products. To the extent that any products may be regulated as both a battery charger and an EPS, DOE may consider the treatment of those products as part of its further consideration of these energy conservation standards.

e. Final EPS Product Classes

DOE is establishing eight product classes for EPSs for the reasons discussed above. The eight EPS product classes are listed in Table IV–1.

TABLE IV–1—EXTERNAL POWER SUPPLY PRODUCT CLASSES

Class ID	Product class
B	Direct Operation, AC–DC, Basic-Voltage.
C	Direct Operation, AC–DC, Low-Voltage (except those with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps that charge the battery of a product that is fully or primarily motor operated).
C-1	Direct Operation, AC–DC, Low-Voltage with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps and charges the battery of a product that is fully or primarily motor operated.
D	Direct Operation, AC–AC, Basic-Voltage.
E	Direct Operation, AC–AC, Low-Voltage.
X	Direct Operation, Multiple-Voltage.
H	Direct Operation, High-Power.
N	Indirect Operation.

DOE is also adopting definitions for the following terms: Basic-voltage external power supply, direct operation external power supply, indirect operation external power supply, and low-voltage external power supply. These definitions will appear at 10 CFR 430.2. DOE proposed, but is not adopting, definitions for AC–AC external power supply, AC–DC external power supply, and multiple-voltage external power supply because similar terms have already been codified. See definitions for single-voltage external AC–AC power supply, single-voltage external AC–DC power supply, and multiple-voltage external power supply at 10 CFR 430 Subpart B Appendix Z.

3. Technology Assessment

In the technology assessment, DOE identifies technology options that appear to be feasible to improve product efficiency. This assessment provides the technical background and structure on which DOE bases its screening and engineering analyses. The following discussion provides an overview of the technology assessment for EPSs. Chapter 3 of the TSD provides additional detail and descriptions of the basic construction and operation of EPSs, followed by a discussion of technology options to improve their efficiency and power consumption in various modes.

a. EPS Efficiency Metrics

DOE used its EPS test procedures as the basis for evaluating EPS efficiency over the course of the standards rulemaking for EPSs. These procedures, which are codified in appendix Z to subpart B of 10 CFR Part 430 ("Uniform Test Method for Measuring the Energy Consumption of EPSs"), include a means to account for the energy consumption from single-voltage EPSs, switch-selectable EPSs, and multiple-voltage EPSs.

On December 8, 2006, DOE codified a test procedure final rule for single output-voltage EPSs. See 71 FR 71340. On June 1, 2011, DOE added a test procedure to cover multiple output-voltage EPSs. See 76 FR 31750. DOE's test procedures yield two measurements: Active mode efficiency and no-load mode (standby mode) power consumption.

Active-mode efficiency is the ratio of output power to input power. For single-voltage EPSs, the DOE test procedure averages the efficiency at four loading conditions—25, 50, 75, and 100 percent of maximum rated output current—to assess the performance of an EPS when powering diverse loads. For multiple-voltage EPSs, the test procedure provides those four metrics individually, which DOE averages to measure the efficiency of these types of devices. The test procedure also specifies how to measure the power consumption of the EPS when disconnected from the consumer product, which is termed "no-load" power consumption because the EPS outputs zero percent of the maximum rated output current to the application.

To develop the analysis and to help establish a framework for setting EPS standards, DOE considered both combining average active-mode efficiency and no-load power into a single metric, such as unit energy consumption (UEC), and maintaining separate metrics for each. DOE chose to evaluate EPSs using the two metrics separately. Using a single metric that combines active-mode efficiency and no-load power consumption to determine the standard may inadvertently permit the "backsliding" of the standards established by EISA 2007. Specifically, because a combined metric would regulate the overall energy consumption of the EPS as the aggregation of active-mode efficiency and no-load power, that approach could permit the performance of one metric to drop below the EISA 2007 level if it is sufficiently offset by an improvement in the other metric. Such a result would, in DOE's view, constitute a backsliding of the standards and would violate EPCA's prohibition from setting such a level. DOE's approach seeks to avoid this result.

The DOE test procedure for multiple-voltage EPSs yields five values: no-load power consumption as well as efficiency at 25, 50, 75, and 100 percent of maximum load. In the March 2012 standards NOPR, DOE proposed averaging the four efficiency values to create an average efficiency metric for multiple-voltage EPSs, similar to the approach followed for single-voltage EPSs. Alternatively, DOE introduced the idea of averaging the efficiency measurements at 50 percent and 75 percent of maximum load because the only known application that currently uses a multiple-voltage EPS, a video game console, operates most often between those loading conditions. DOE sought comment from interested parties on these two approaches.

Microsoft commented that setting a standard based on arbitrary loads that do not represent the intended loading

point of the end-use application is counterproductive because EPSs are designed to be most efficient under the loading conditions they operate in most frequently. Instead, Microsoft believes that "to optimize energy savings in real life, loading requirements in energy conservation standards should be based on the expected product load." (Microsoft, No. 110 at p. 2)

Although it is aware of only one currently available consumer product using multiple-voltage EPSs, DOE believes that evaluating multiple-voltage EPSs using an average-efficiency metric (based on the efficiencies at 25%, 50%, 75%, and 100% of each output's normalized maximum nameplate output power) would allow the standard to be applied to a diverse range of future products that may operate under different loading conditions. In addition, DOE's test data of the only product that currently falls into the multiple-voltage product class indicate that there is only a fractional percentage difference in the average active-mode efficiency when comparing DOE's weighting of the efficiency loading measurements and the alternative approach of averaging the efficiencies at 50% and 75% load where the console is most likely to operate. Therefore, DOE evaluated multiple-voltage EPSs using no-load mode power consumption and an average active-mode efficiency metric based on the measured efficiencies at 25%, 50%, 75%, and 100% of rated output power in developing the new energy conservation standards for these products. This loading point averaging methodology is consistent with the calculation of average active-mode efficiency for single-voltage external supplies as outlined in Appendix Z to Subpart B of 10 CFR Part 430.

b. EPS Technology Options

DOE considered seven technology options, fully detailed in Chapter 3 of the TSD, which may improve the efficiency of EPSs: (1) Improved Transformers, (2) Switched-Mode Power Supplies, (3) Low-Power Integrated Circuits, (4) Schottky Diodes and Synchronous Rectification, (5) Low-Loss Transistors, (6) Resonant Switching, and (7) Resonant ("Lossless") Snubbers.

During its analysis, DOE found that some technology options affect both efficiency and no-load performance and that the individual contributions from these options cannot be separated from each other in a cost analysis. Given this finding, DOE adopted a "matched pairs" approach for defining the EPS CSLs. This approach used selected test units to characterize the relationship between average active-mode efficiency and no-load power dissipation. In the matched pairs approach, EPS energy consumption decreases as you move from one CSL to the next higher CSL either through higher active mode efficiency, lower no-load mode power consumption, or both. If DOE allowed one metric to decrease in stringency between CSLs, then the cost-efficiency results might have shown cost reductions at higher CSLs and skewed the true costs associated with increasing the efficiency of EPSs. To avoid this result, DOE used an approach that increases the stringency of both metrics for each CSL considered during the process of amending the EISA standard for EPSs.

DOE considered all technology options when developing CSLs for all four EPS representative units in product class B. DOE considered the same efficiency improvements in its analysis for EPSs in product classes X and H as it did for Class A EPSs. Where representative units were not explicitly analyzed (*i.e.,* product classes C, D, and E), DOE extended its analysis from a directly analyzed class. As a result, all design options that could apply to these products were implicitly considered because the efficiency levels of the analyzed product class will be scaled to other product classes, an approach supported by interested parties throughout the rulemaking process. The equations were structured based on the relationships between product classes C, D, and E and representative product class B such that the technology options not implemented by the other classes were accounted for in the proposed candidate standard levels. For example, AC–AC EPSs (product classes C and E) tend to have higher no-load power dissipation than AC–DC EPSs because they do not use switched-mode topologies (see Chapter 3 of the TSD for a full technical description). Therefore, to account for this characteristic in these products, DOE used higher no-load power metrics when generating CSLs for these product classes than are found in the corresponding CSLs for the representative product class B.

c. High-Power EPSs

DOE examined the specific design options for high-power EPSs as they relate to ham radios, the sole consumer application for these EPSs. DOE found that high-power EPSs are unique because both linear and switched-mode versions are available as cost-effective options, but the linear EPSs are more expensive and inherently limited in their achievable efficiency despite sharing some of the same possible efficiency improvements as EPSs in other product classes.[20] Interested parties have expressed concern that setting an efficiency standard higher than a linear EPS can achieve would reduce the utility of these devices because ham radios are sensitive to the electromagnetic interference (EMI) generated by switched-mode EPSs. In some cases, EMI can couple through the EPS to the transmitter of ham radios and be transmitted on top of the intended signal causing distortion.

DOE sought comment on the impacts of excessive EMI in amateur radio applications using EPSs with switched-mode topologies. PTI acknowledged that EMI generated from switched-mode power supplies is more of a factor in radio applications, but could not definitively attest to any adverse impacts on consumer utility due to the changeover from linear power supplies. (PTI, No. 133 at p. 4)

DOE believes there is no reduction in utility because EPSs used in telecommunication applications are required to meet the EMI regulations of the Federal Communications Commission (47 CFR part 15, subpart B), regardless of the underlying technology. These regulations specifically limit the amount of EMI for "unintentional radiators", which are devices that are not intended to generate radio frequency signals but do to some degree due to the nature of their design. Many such devices limit the amount of EMI coupled to the end use product through EMI filters and proper component arrangement on the printed circuit board (PCB). As part of its engineering analysis, DOE constructed the high power cost-efficiency curves using two teardown units including one that utilized switched-mode technology and made use of similar EMI-limiting techniques. This switched-mode design complied with the FCC requirements with no reduction in utility or performance despite a higher efficiency than the baseline design DOE analyzed. Given the presence of switched-mode designs that comply with the FCC regulations and the existence of EMI-limiting technology, DOE does not believe that the new standard will negatively affect the consumer utility of high-power EPSs.

d. Power Factor

Power factor is a relative measure of transmission losses between the power plant and a consumer product or the

[20] A linear mode or linear regulated EPS is an EPS that has its resistance regulated and results in a constant output voltage. In contrast, a switched mode EPS is an EPS that switches on and off to maintain an average value of output voltage.

ratio of real power to the total power drawn by the EPS. Due to nonlinear and energy-storage circuit elements such as diodes and inductors, respectively, electrical products often draw currents that are not proportional to the line voltage. These currents are either distorted or out of phase in relation to the line voltage, resulting in no real power drawn by the EPS or transmitted to the load. However, although the EPS itself consumes no real power, these currents are real and cause power dissipation from conduction losses in the transmission and distribution wiring. For a given nameplate output power and efficiency, products with a lower power factor cause greater power dissipation in the wiring, an effect that also becomes more pronounced at higher input powers. DOE examined the issue of power factor in section 3.6 of the May 2009 framework document for the present rulemaking and noted that certain ENERGY STAR specifications limit power factor.

DOE notes that regulating power factor includes substantial challenges, such as quantifying transmission losses that depend on the length of the transmission wires, which differ for each residential consumer. Further, DOE has not yet conclusively analyzed the benefits and burdens from regulating power factor. While DOE plans to continue analyzing power factor and the merits of its inclusion as part of a future rulemaking, it is DOE's view that the above factors weigh in favor of not setting a power factor-based standard at this time.

B. Screening Analysis

DOE uses the following four screening criteria to determine which design options are suitable for further consideration in a standards rulemaking:

1. *Technological feasibility.* DOE considers technologies incorporated in commercial products or in working prototypes to be technologically feasible.

2. *Practicability to manufacture, install, and service.* If mass production and reliable installation and servicing of a technology in commercial products could be achieved on the scale necessary to serve the relevant market at the time the standard comes into effect, then DOE considers that technology practicable to manufacture, install, and service.

3. *Adverse impacts on product utility or product availability.* If DOE determines a technology would have significant adverse impact on the utility of the product to significant subgroups of consumers, or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not consider this technology further.

4. *Adverse impacts on health or safety.* If DOE determines that a technology will have significant adverse impacts on health or safety, it will not consider this technology further. See 10 CFR part 430, subpart C, appendix A, (4)(a)(4) and (5)(b).

For EPSs, DOE did not screen out any technology options after considering the four criteria. For additional details, see chapter 4 of the TSD.

Brother International commented that the design options DOE considered for lowering no-load power consumption could adversely impact the health and safety of consumers as manufacturers might eliminate existing safety controls to comply with the amended standards. Specifically, citing to one example, Brother pointed to the lack of a device to discharge residual charge from one of their candidate EPS designs, which they believed was removed in order to comply with the proposed no-load requirements from the NOPR. Brother believes this omission could impact safety to consumers and that DOE should not lower the no-load requirements for EPSs below the current federal maximum of 0.5 watts. However, they did not elaborate on the component involved or state that removing said component was the only design option in order to meet the proposed standard. (Brother International, No. 111 at p. 3)

DOE conducts a screening analysis on all the technology options it identifies during the technology assessment portion of the rulemaking by applying a strict set of statutory criteria. At no point during interviews with manufacturers or DOE's independent testing, was there concern expressed over the no-load levels DOE was analyzing. The no-load power metric for each CSL DOE considered was supported by data compiled from already commercially available units, which posed no such health or safety risk to consumers. While Brother International did not expand on its concerns, DOE is aware of certain components in general EPS design, such as X capacitors and bleeder resistors. EPS designers typically use X capacitors on the input filter stages to protect the EPS against line voltage spikes and bleeder resistors to bleed off the residual charge from the devices when the EPS is disconnected. It is common design to practice to include these components; however, should the resistor be omitted, the capacitors will still discharge within seconds of the power being removed. In any case, based on its examination of this issue, DOE does not believe these design practices present any shock hazard to consumers provided they do not attempt to physically tear down or otherwise destroy the EPS under live power conditions. As a result, DOE did not screen out any additional technology options based on adverse impacts to health and safety associated with decreasing the no-load power consumption through the amended EPS standards.

Additionally, DOE notes that it has received no comments from interested parties regarding patented technologies and proprietary designs that would inhibit manufacturers from achieving the energy conservation standards adopted in today's rule. DOE believes that those standards will not mandate the use of any such technologies.

C. Engineering Analysis

In the engineering analysis (detailed in chapter 5 of the TSD), DOE describes the relationship between the manufacturer selling price (MSP) and increases in EPS efficiency. The efficiency values range from that of an inefficient EPS sold today (the baseline) to the maximum technologically feasible efficiency level. For each efficiency level examined, DOE determines the MSP; this relationship is referred to as a cost-efficiency curve.

DOE structured its engineering analysis around two methodologies: (1) Test and teardowns, which involves testing products for efficiency and determining cost from a detailed bill of materials derived from tear-downs and (2) the efficiency-level approach, where the cost of achieving increases in energy efficiency at discrete levels of efficiency are estimated using information gathered in manufacturer interviews supplemented by, and verified through, technology reviews and subject matter experts (SMEs). When analyzing the cost of each CSL—whether based on existing or theoretical designs—DOE distinguishes between the cost of the EPS and the cost of the associated end-use product.

1. Representative Product Classes and Representative Units

DOE selected representative product class B (AC to DC conversion, basic-voltage EPSs), which contains most Class A EPSs and some MADB EPSs that can directly power an application, as the focus of its engineering analysis because it constituted the majority of shipments and national energy

consumption related to EPSs. Within product class B, DOE analyzed four representative units with output powers of 2.5 watts, 18 watts, 60 watts, and 120 watts because the associated consumer applications for these, and similar, EPSs constitute a significant portion of shipments and energy consumption. Based on DOE's analysis of product class B, DOE was able to scale the results for product classes C, D, and E. EPSs in each have inherent technical limitations that prevent them from meeting the same efficiency and no-load levels as EPSs in product class B. The lower-voltage product classes C and E typically have higher loss ratios than EPSs in product class B due to their lower nameplate output voltages and higher nameplate output currents. Therefore, it was necessary for DOE to scale down the efficiency levels established in product class B to more technically achievable levels for product classes C and E.

Similarly, EPSs in product class D do not possess control circuitry to lower the no-load power consumption. DOE found that including such circuitry would increase the no-load consumption while increasing the overall cost of EPSs in product class D. DOE subsequently scaled the no-load power consumption results established from the analysis of product class B to adjust for this limitation of EPSs in product class D. Despite the comparatively small percentage of EPSs in product classes C, D, and E compared to those in product class B, DOE has taken steps to ensure that the standards for each class are technically feasible for EPSs in each product class. More detail on DOE's scaling methodology can be found in chapter 5 of the final rule TSD.

Some interested parties supported DOE's approach in creating and analyzing representative product classes and representative units during the rulemaking process. The California IOUs agreed with using product class B as the representative product class and scaling to other product classes because of their inherent similarities. (CA IOUs, No. 138 at p. 13) Although no specific data were provided, the California IOUs also commented in support of the four representative units within the product class, noting that their own research [21] into the power supply market corroborates DOE's selections. (CA IOUs, No. 138 at p. 13) ARRIS Group, however, claimed that "by analyzing EPSs at the 18W representative unit, DOE overstates annual power cost savings" and suggested that averaging energy savings across output powers is more accurate. (ARRIS Group, No. 105 at p. 2) Both of the methodologies DOE presented during the NOPR public meeting were identical to those originally drafted as part of the preliminary analysis.

The representative units DOE selected align with a wide range of EPS output powers for consumer applications. The purpose was to select units that capture the most common output voltages and output powers available on the market. In most cases, as output power increases, nameplate output voltage also increases, but DOE found that most EPS designs tended to cluster around certain common output voltage and output power levels. DOE used this trend in EPS design to categorize its four representative units. DOE was also able to test several EPS units that exactly met the representative units' specifications and scaled units with small variations based on output power, output voltage, cord length, and/or cost as described in chapter 5 of the final rule TSD. While the costs are analyzed on an individual unit basis, the standard levels considered by DOE, and ultimately the energy savings, are examined across the entire range of EPSs. National energy savings (NES) and consumer NPV are calculated for an entire product class, not an individual representative unit. To date, stakeholders have supported this approach and the overall engineering analysis methodology. Therefore, DOE elected to maintain its selections for the EPS representative units and its methodology for estimating the cost savings from the standards adopted today.

2. EPS Candidate Standard Levels (CSLs)

DOE applied the same methodology to establish CSLs in today's final rule as it did for its proposal and preliminary analysis. DOE created CSLs as pairs of EPS efficiency metrics for each representative unit with increasingly stringent standards having higher-numbered CSLs. The CSLs were generally based on (1) voluntary (e.g. ENERGY STAR) specifications or mandatory (*i.e.*, those established by EISA 2007) standards that either require or encourage manufacturers to develop products at particular efficiency levels; (2) the most efficient products available in the market; and (3) the maximum technologically feasible ("max tech") level. These CSLs are summarized for each representative unit in Table IV–2. In section IV.C.5, DOE discusses how it developed equations to apply the CSLs from the representative units to all EPSs.

TABLE IV–2—SUMMARY OF EPS CSLS FOR PRODUCT CLASSES B, C, D, AND E

CSL	Reference	Basis
0	EISA 2007	EISA 2007 equations for efficiency and no-load power.
1	ENERGY STAR 2.0	ENERGY STAR 2.0 equations for efficiency and no-load power.
2	Intermediate	Interpolation between test data points.
3	Best-in-Market	Most efficient test data points.
4	Max Tech	Maximum technologically feasible efficiency.

DOE conducted several rounds of interviews with manufacturers who produce EPSs, integrated circuits for EPSs, and applications using EPSs. All of the manufacturers interviewed identified ways that EPSs could be modified to achieve efficiencies higher than those available with current products. These manufacturers also described the costs of achieving those efficiency improvements, which DOE examines in detail in chapter 5 of the TSD. DOE independently verified the accuracy of the information described by manufacturers.[22] Verifying this information required examining and testing products at the best-in-market efficiency level and determining what

[21] *http://www.energy.ca.gov/appliances/archive/2004rulemaking/documents/case_studies/CASE_Power_Supplies.pdf.*

[22] In confirming this information, DOE obtained technical assistance from two subject matter experts—These two experts were selected after having been found through the Institute of Electrical and Electronics Engineers (IEEE). Together, they have over 30-years of combined experience with power supply design. The experts relied on their experience to evaluate the validity of both the design and the general cost of the max-tech efficiency levels provided by manufacturers.

design options could still be added to improve their efficiency. By comparing the improved best-in-market designs (using predicted performance and cost) to the estimates provided by manufacturers, DOE was able to assess the reasonableness of the max-tech levels developed.

DOE created the max-tech candidate standard level (CSL 4) equations for average efficiency and no-load power using curve-fits (*i.e.*, creating a continuous mathematical expression to represent the trend of the data as accurately as possible) of the aggregated manufacturer data (see chapter 5 of the TSD for details on curve fits). DOE created the equations for no-load power based on a curve fit of the no-load power among the four representative units. For both the average efficiency and no-load power CSL equations, DOE used equations similar to those for CSL 1, involving linear and logarithmic terms in the nameplate output power. DOE chose the divisions at 1 watt and 49 watts in the CSL 4 equations to ensure consistency with the nameplate output power divisions between the equations for CSL 1.

DOE evaluated EPSs using the two EPS efficiency metrics, no-load power consumption and active-mode average efficiency, which it grouped into "matched pairs." Under the matched pairs approach, each CSL would increase in stringency in at least one of the metrics and no metric would ever be lowered in moving to a higher CSL. DOE's goal in using this approach was to ensure that when it associated costs with the CSLs, that the costs would reflect the complete costs of increased efficiency. If DOE followed an approach that permitted a decrease in stringency for a given metric, the result might be a projected reduction in EPS cost, which would mask the full cost of increasing EPS efficiency.

Interested parties supported DOE's matched pairs approach for EPS CSLs. Stakeholders, such as the California Energy Commission, commented that DOE's approach focused directly on what is measured rather than introducing usage assumptions to weight the values of standby mode and active-mode power consumption. The California Energy Commission believes that regulating active-mode efficiency and no-load power consumption rather than a combined unit energy consumption (UEC) metric is the most appropriate course of action for DOE (California Energy Commission, No. 117 at p. 17). While supportive of DOE's approach, interested parties, including the California IOUs, also cautioned DOE to avoid setting levels for no-load power that were too stringent when compared to active-mode efficiency improvements. (CA IOUs, No. 138 at p. 13)

DOE received additional comments regarding its EPS CSLs. NRDC and ASAP both urged DOE to "evaluate an intermediate level for EPS product class B between CSL 3 and CSL 4", suggesting that there may be a more stringent standard that is cost-effective between DOE's estimates for the best-in-market and maximum technologically feasible CSLs. (NRDC, No. 114 at p. 12; ASAP, *et al.*, No. 136 at p. 10)

As discussed above, DOE's CSL equations are a function of nameplate output power and are based on existing standards, incentive programs, the most efficient tested units on the market, intermediate levels between those points, and a maximum technologically feasible or "max-tech" level. No-load requirements were carefully considered consistent in light of the submitted comments. The difference in performance between the CSLs noted by NRDC corresponds to the difference between the best-in-market level, which is supported by test data, and the "max-tech" level, which is theoretical and based on estimates from manufacturers and industry experts. DOE's comprehensive engineering analysis selected specific CSLs based on real world data and discussions with manufacturers. NRDC did not provide any additional data to support its recommendation that DOE examine more stringent standard. Instead, it asserted that DOE did not find more efficient EPSs on the market above the CSL proposal because market demand is shaped primarily by the efficiency marking protocol and there is currently little incentive for the market to demand efficiencies higher than Level V. (NRDC, No. 114 at p. 12)

In DOE's view, adopting NRDC's approach would create a standard based entirely on theoretical design improvements to the most efficient EPSs already on the market today. Such an approach would not be supportable by any actual data—whether market-based or through the testing of available products. DOE notes that since a second determination is required in 2015, any further analysis of efficiency levels beyond the current best-in-market CSL would likely occur as part of that effort. As a result, based on currently available information, DOE chose to maintain its CSLs in the engineering analysis for today's final rule.

Brother International expressed concern that requiring more efficient EPSs in line with the proposed minimum efficiency active-mode limits would disrupt the stable product supply due to the lack of non-proprietary semiconductors (Brother International, No. 111 at p. 3). It noted that there is one key component needed to meet the proposed efficiency levels for EPSs, and that it has been told by EPS suppliers that there are a small number of component manufacturers that can produce this patented technology. Brother International did not provide any evidence to support this. However, during manufacturer interviews, DOE was consistently told the candidate standard levels (CSLs) analyzed for EPSs were technically achievable without the use of patented technologies. Each component manufacturer, original design manufacturer (ODMs), or those that design and manufacturer EPSs based on a set of specifications, and original equipment manufacturers (OEMs), or those that purchase EPSs from ODMs to be solid in retail markets, interviewed had different pathways to achieving the proposed standard suggesting there are multiple design options to lower EPS energy consumption. At no point in discussions with manufacturers has DOE been told that a patented technology would be required to meet a CSL for any of the product classes, even at the maximum technologically feasible level.

DOE also maintained the same CSLs for multiple-voltage EPSs (product class X) as it proposed in the NOPR because it received no comments and has no new information that would merit a change in the CSLs for this product class. The CSLs are shown in Table IV–3.

TABLE IV–3—SUMMARY OF EPS CSLS FOR PRODUCT CLASS X

CSL	Reference	Basis
0	Market Bottom	Test data of the least efficient unit in the market.
1	Mid-Market	Test data of the typical unit in the market.
2	Best-in-Market	Manufacturer's data.

TABLE IV–3—SUMMARY OF EPS CSLS FOR PRODUCT CLASS X—Continued

CSL	Reference	Basis
3	Max Tech	Maximum technologically feasible efficiency.

DOE received no comments concerning the CSLs for high-power EPSs in response to the NOPR. Therefore, DOE maintained its selections for CSLs from the NOPR in the engineering analysis for today's final rule. The CSLs for product class H are listed in Table IV–4.

TABLE IV–4—SUMMARY OF EPS CSLS FOR PRODUCT CLASS H

CSL	Reference	Basis
0	Line Frequency	Test data of a low-efficiency unit in the market.
1	Switched-Mode Low Level	Test data of a high-efficiency unit in the market.
2	Switched-Mode High Level	Manufacturers' theoretical maximum efficiency.
3	Scaled Best-in-Market	Scaled from 120W EPS CSL 3.
4	Scaled Max Tech	Scaled from 120W EPS CSL 4.

3. EPS Engineering Analysis Methodology

DOE relied upon data gathered from manufacturer interviews to construct its engineering analysis for EPSs. DOE's cost-efficiency analysis for each of the representative units in product class B was generated using aggregated manufacturer cost data. DOE attempted to corroborate these estimates by testing and tearing down several EPSs on the market. For those products that did not exactly match its representative units, DOE scaled the test results for output power, output voltage, and cord length as necessary to align with the representative unit specifications. The units were then torn down by iSuppli to estimate the manufacturer selling price (MSP) and create a unique cost-efficiency curve entirely based on measurable results. The test and teardown data were inconclusive and generally showed decreasing costs with increasing efficiency. DOE previously presented both sets of cost-efficiency data to stakeholders for comment and consistently received support for using the manufacturer data as the basis for any standard setting action. Stakeholders argued that the negative cost-efficiency trends seen in the teardown data were not representative of the EPS market and that the manufacturer data was much more consistent and reliable since the data were more comprehensive. Stakeholders indicated that the data collected from manufacturer interviews better reflected the industry trends because it was derived from the estimates of manufacturers who produce EPSs in volume rather than backed out from an overall BOM cost by iSuppli. Therefore, in section IV.C of the NOPR, DOE proposed to use only the data gathered from manufacturers for its engineering analysis.

With respect to the scaled test results, Salcomp disagreed with DOE's results, stating that the "scaled average efficiency results in the reference data are not in line with theoretical calculations related to 5V/1A EPSs" and that "it appears that the real effects of the cable have not been taken into account." Salcomp also proposed that USB–A EPS products be measured without the cable, as EPS manufacturers do not know anything about the cables that are ultimately supplied with the product. (Salcomp, No. 73 at p. 1)

NRDC suggested that the teardowns commissioned by DOE for the cost-efficiency curves were not conducted on EPSs of comparable utility, but commented that up-to-date manufacturer data should be sufficient to conduct an accurate cost-efficiency analysis going forward. (NRDC, No. 114 at p. 11)

As stated in DOE's test procedure for single-voltage EPSs, "power supplies must be tested in their final, completed configuration in order to represent their measured efficiency on product labels or specification sheets." (74 FR 13318) USB–A EPSs must, therefore, be tested with the USB cable, as supplied by the manufacturer of the EPS, connected. DOE took this into account as part of its engineering analysis methodology and established a representative DC cable length to help scale the measured efficiency of an EPS based on its nameplate output power and output voltage. As described in chapter 5 of the TSD, the resistivity of a wire is dependent on the resistivity of the copper used, the length of the wire, and the cross-sectional area of the wire. With all other factors the same, a longer cord length would increase the resistivity of the wire and subsequently increase the losses associated with the output cord, ultimately lowering the conversion efficiency of the EPS. Scaling the measured efficiency using a standard cable length meant that DOE needed to factor in any expected resistive losses associated with the current provided by the EPS in question. However, the scaling was applied not to correct for potential cable losses, but to take efficiency data measured with the manufactured cable and adjust it to the standard length. In all cases, the output cord loss was taken into account in the efficiency results of the EPSs DOE tested. Ultimately, these data were only used to support DOE's CSLs and not directly factored into the cost-efficiency curves DOE used to select standard levels for EPSs. DOE relied only on manufacturer interview data in its cost-efficiency analysis.

4. EPS Engineering Results

DOE characterized the cost-efficiency relationship of the four representative units in product class B as shown in Table IV–5, Table IV–6, Table IV–7, and Table IV–8. During interviews, manufacturers indicated that their switched-mode EPSs currently meet CSL 1, the ENERGY STAR 2.0 specification level. This factor is reflected in the analysis by setting the incremental MSP for the 18W, 60W, and 120W EPSs to $0 at CSL 1, which means that there is no incremental cost above the baseline to achieve CSL 1. Costs for the 2.5W EPS, however, are estimated at $0.15 for CSL 1. This result occurs because of DOE's assumption (based on available information) that the lowest cost solution for improving the efficiency of the 2.5W EPS is through the use of linear EPSs, which are manufactured both at the EISA 2007

level as well as the ENERGY STAR 2.0 level. Specifically, as commenters suggested, DOE examined linear EPSs and found that they might be a cost-effective solution at CSL 0 and CSL 1 for 2.5W EPSs. Thus, $0.15 indicates the incremental cost for a 2.5W linear EPS to achieve higher efficiency. For all four representative units, the more stringent CSLs—CSL 2, CSL 3, and CSL 4—correspond to switched-mode EPSs designed during the same design cycle, which would cause their costs to increase with increased efficiency as more efficient designs require more efficient and more expensive components.

Table IV-5 2.5W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3	CSL 4
Efficiency [%]:	58.3	67.9	71.0	73.5	74.8
No-Load Power [W]:	0.500	0.300	0.130	0.100	0.039
CSL Description:	EISA	ENERGY STAR 2.0	Intermediate	Best-in-Market	Max Tech
Incremental MSP[$]:	0.00	0.15	0.33	0.45	0.52

Table IV-6 18W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3	CSL 4
Efficiency [%]:	76.0	80.3	83.0	85.4	91.1
No-Load Power [W]:	0.500	0.300	0.200	0.100	0.039
CSL Description:	EISA	ENERGY STAR 2.0	Intermediate	Best-in-Market	Max Tech
Incremental MSP[$]:	0.00	0.00	0.17	0.64	2.89

Table IV-7 60W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3	CSL 4
Efficiency [%]:	85.0	87.0	87.0	88.0	92.2
No-Load Power [W]:	0.500	0.500	0.200	0.073	0.050
CSL Description:	EISA	ENERGY STAR 2.0	Intermediate	Best-in-Market	Max Tech
Incremental MSP[$]:	0.00	0.00	0.13	0.33	1.43

Table IV-8 120W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3	CSL 4
Efficiency [%]:	85.0	87.0	88.0	88.4	93.5
No-Load Power [W]:	0.500	0.500	0.230	0.210	0.089
CSL Description:	EISA	ENERGY STAR 2.0	Intermediate	Best-in-Market	Max Tech
Incremental MSP[$]:	0.00	0.00	0.31	0.45	6.41

NRDC had a number of comments on DOE's cost-efficiency results from the NOPR. In general, NRDC asserted that DOE had overestimated the cost of efficiency improvements for the 2.5 watt, 18 watt, and 60 watt representative units, based on NRDC's own discussions with industry professionals. (NRDC, No. 114 at p. 11) In some cases, DOE's estimates for the incremental MSPs are nearly three times greater than NRDCs estimates. ASAP, who echoed these concerns, stated that the costs of highly efficient EPSs are rapidly declining and that DOE should reevaluate its estimates to reflect the most recent price trends. (ASAP, *et al.*, No. 136 at p. 10)

While ASAP and NRDC had comments concerning the cost-efficiency relationships of several representative units, many stakeholders mentioned the 60 watt representative unit cost-efficiency curves as being particularly skewed. NRDC stated that the fact that the 60 watt costs were higher than the 120 watt costs for most CSLs was not accurate, as higher power EPSs require higher material costs. They noted that perhaps DOE's analysis of the 60 watt unit included features unrelated to efficiency, which would explain the higher than expected costs for the lower order CSLs. (NRDC, No. 114 at p. 11) The PSMA submitted similar comments stating that the incremental costs for EPSs increase "steadily and predictably with power supply size" such that the 60 watt incremental costs should be lower than those for the 120 watt

representative unit. (PSMA, No. 147 at p. 2) NEEP commented that the LCC results derived from the cost-efficiency curves for the 60 watt representative unit show unexplained irregularities that were attributed to manufacturer-provided cost data and suggested DOE conduct an additional independent engineering analysis on the 60 watt discrepancy. (NEEP, No. 160 at p. 2) These comments were based on the negative weighted-average LCC savings for the 60W representative unit at all CSLs above the baseline. DOE believes these results were due to the large incremental cost associated with moving from CSL 1 to CSL 2 and the relatively small increases in cost for the higher order CSLs.

DOE aggregated costs from OEMs, ODMs and component manufacturers to reflect the costs associated with incremental improvements in the energy efficiency of four representative units within product class B. Those costs were presented as the manufacturer selling price (MSP), or the price that the OEM pays the ODM for an EPS that meets its specifications. These costs were estimated through a series of manufacturer interviews to establish a range of average markups and incremental costs for efficiency improvements. The MSPs gleaned from interviews included only improvements to efficiency-related components over the manufacturer's baseline EPS model. Therefore, the incremental costs in DOE's analyses are only representative of improvements to the energy efficiency of EPSs.

DOE took the stakeholder comments into consideration when revising its engineering analysis for today's final rule. NRDC's assertion that the costs are overestimated for the 2.5W EPS representative unit fails to acknowledge that certain linear power supplies are still cost-effective and technically feasible for efficiencies up to CSL 1 for low power EPSs. The final cost-efficiency curve incorporates not only changes to switched-mode designs for higher efficiencies, but costs incurred by manufacturers of linear power supplies to improve the efficiency over the current designs. The result of this aggregation shows higher overall costs than estimated by NRDC for this representative unit.

In revisiting the cost-efficiency curves, DOE noted that the 60W cost aggregation contained the largest concentration of data from manufacturer interviews conducted during the preliminary analysis. Since the LCC results for the 60W representative unit largely depend on the cost changes between the CSLs and the efficiency distribution of the current products on the market, DOE decided to revise its aggregation using only the most recent data gathered from manufacturer interviews to generate the cost-efficiency curves presented in today's final rule. DOE believes that these curves better reflect the cost impacts of improving the efficiency of 60W EPSs and notes they align with NRDC's incremental MSP estimates for achieving the efficiency level of the amended standard. The resulting cost-efficiency curve shows a substantially smaller incremental cost at the proposed standard level of $0.33 compared to $1.29 in the NOPR. This modification caused the life-cycle cost savings at the proposed standard level for the 60W representative unit to turn strongly positive from the negative result depicted in the NOPR. The full LCC impacts can be found in Section V.B.1.a. For the 2.5W, 18W, and 120W representative units, DOE maintained its cost estimates from the NOPR because they represent the aggregated results from DOE's most recent data gathering efforts.

Unlike product class B, DOE analyzed only a single 203W representative unit for multiple-voltage EPSs. In Chapter 5 of the TSD, DOE outlines the cost-efficiency relationship for 203W multiple-voltage EPSs that it developed as part of the non-Class A EPS determination analysis. DOE received no comments on its engineering results for this product class and, therefore, maintained the same results in today's final rule. The results for the 203W multiple-voltage EPS product class are shown in Table IV–9.

Table IV-9 203W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3
Efficiency [%]:	82.4	86.4	86.4	88.5
No-Load Power [W]:	12.33	0.400	0.300	0.300
CSL Description:	Market Baseline	Mid-Market	Best-in-Market	Max Tech
Incremental MSP[$]:	0.00	2.45	2.66	7.71

Similar to the analysis of multiple-voltage EPSs, DOE analyzed one 345W representative unit for high-power EPSs. In chapter 5 of the NOPR TSD, DOE indicated that it was considering applying the cost-efficiency relationship for 345W high-power single-voltage EPSs that it developed as part of the non-Class A EPS determination analysis to high-power EPSs. In the determination analysis, DOE derived costs for CSL 0 and CSL 1 from test and teardown data, whereas costs for CSL 2 and CSL 3 came from manufacturer and component supplier interviews. DOE did not receive comments on this aspect of its approach in the NOPR. Hence, DOE used the results from the determination analysis to characterize the costs of the less-efficient CSLs for 345W high-power EPSs (CSL 0 and CSL 1) for today's final rule.

After discussions with its subject matter experts (SMEs), DOE believes that a 345W EPS can achieve higher efficiencies based on a theoretical model of a 360W EPS that exhibits the properties of three 120W EPSs connected in parallel. This model essentially demonstrates a "black box" approach that supplies the representative unit output voltage at a higher output current than a single 120W unit would be able to provide. As each EPS in this system would be operating at an identical efficiency, the system as a whole would meet the same efficiency as any one EPS and, therefore, the 345W unit can be modeled as several 120W EPSs connected in parallel.

These higher output devices are typically used with amateur radio equipment, which often transmit at power levels between 100 and 200 watts while simultaneously providing power to other components. DOE developed its costs for the higher-efficiency CSLs (CSL 2, CSL 3, and CSL 4) based on its 120W EPS analysis. DOE received no comments on this approach and thus retained the cost-efficiency relationship for the 345W EPS shown in Table IV–10 for today's final rule.

Table IV-10 345W EPS Engineering Analysis Results

	CSL 0	CSL 1	CSL 2	CSL 3	CSL 4
Efficiency [%]:	62.4	81.3	84.6	87.5	92.0
No-Load Power [W]:	15.43	6.01	0.500	0.500	0.266
CSL Description:	Market Baseline	Low Market	Mid-Market	Scaled Best-in-Market	Scaled Max Tech
Absolute MSP[$]:	132.68	104.52	104.52	107.30	143.92

5. EPS Equation Scaling

In support of the NOPR, DOE presented an approach to deriving the average efficiency and no-load power consumption requirements for each CSL over the full range of output power for Class A EPSs in chapter 5 of the NOPR TSD. Mathematical equations define each CSL as a pair of relationships that are functions of nameplate output power: (1) Average active-mode efficiency and (2) no-load mode power consumption. These equations allowed DOE to describe a CSL for any nameplate output power and served as the basis for its proposed standards. A complete description of the equations can be found in chapter 5 of the TSD.

For the baseline CSL and CSL 1, DOE relied on equations from EISA 2007 and ENERGY STAR 2.0, respectively, rather than developing new equations. DOE took this approach because EISA created a mandatory standard that established a baseline for DOE's analysis while the ENERGY STAR voluntary program served as an incentive for manufacturers to produce more efficient products in order to brand their products as ENERGY STAR compliant, a quality that that many consumers recognize and seek. Both equations are defined over ranges of output power, although the divisions between ranges are slightly different. EISA 2007 created divisions by establishing efficiency equations with breakpoints at 1 watt and 51 watts; ENERGY STAR 2.0 creates similar divisions at 1 watt and 49 watts. See 42 U.S.C. 6295(u)(3)(A) (creating nameplate output categories of under 1 watt, 1 watt to not more than 51 watts, and over 51 watts) and "ENERGY STAR Program Requirements for Single Voltage External AC–DC and AC–AC Power Supplies" (creating nameplate output categories of less than or equal to 1 watt, 1 watt to not more than 49 watts, and greater than 49 watts). DOE developed equations for all other CSLs and for consistency and simplicity used the ENERGY STAR 2.0 divisions at 1 watt and 49 watts for all CSLs. These divisions were created in conjunction with the EPS product classes discussed in section IV.A.2.a as part of a complete analysis by the EPA when it drafted the ENERGY STAR program requirements for single-voltage external AC–DC and AC–AC power supplies.

DOE derived CSL 2, CSL 3, and CSL 4 by fitting equations to the efficiency values of their respective manufacturer and test data points for each representative unit. DOE used an equation of the form $Y = a*\ln(P_{out}) + b*P_{out} + c$, for each of the nameplate output power ranges, where Y indicates the efficiency requirement; P_{out} indicates the nameplate output power; and a, b, and c represent variables defined for each CSL. DOE ensured that the equations met three conditions:

(1) The distance to each point was minimized.

(2) The equation did not exceed the tested efficiencies.

(3) DOE further restricted the parameter choice in order to ensure that the CSL curves adhered to a matched pairs approach fully detailed in chapter 5 of the TSD.

For the NOPR, DOE derived a revised max-tech scaling equation from data points obtained during manufacturer interviews as noted in section III.B.2.a. DOE received no comments averse to the revised max tech CSL equation. Therefore, DOE has maintained all of its CSL equations from the NOPR in today's final rule.

As in the NOPR, DOE scaled the CSL equations from product class B to the product classes representing low-voltage AC–DC and all AC–AC EPSs (product classes C, D, and E). See Chapter 5 of the TSD to today's final rule for more information regarding DOE's scaling methodology. The scaling for these equations was based on ENERGY STAR 2.0, which separates AC–DC conversion and AC–AC conversion into "basic-voltage" and "low-voltage" categories. ENERGY STAR 2.0 sets less stringent efficiency levels for low-voltage EPSs because they cannot typically achieve the same efficiencies as basic-voltage EPSs due to inherent design limitations. Similarly, ENERGY STAR 2.0 sets less stringent no-load standards for AC–AC EPSs because the devices do not use the overhead circuitry found in AC–DC EPSs to limit no-load power dissipation. As previously stated, the power consumed by the additional AC–AC EPS circuitry would actually increase their no-load power consumption. DOE used this approach to develop CSLs other than the baseline CSL for product classes C, D, and E. Because the EISA 2007 standard applies to all Class A EPSs, which comprise most of product classes B, C, D, and E, the baseline CSL is exactly the same for all four product classes.

As described throughout the EPS rulemaking, DOE created less stringent CSLs for product classes C, D, and E based on the technical differences outlined in Section III.A. The efficiency equations for CSL 1 come directly from the ENERGY STAR 2.0 low-voltage equation because of the impact the ENERGY STAR 2.0 levels had on the EPS market. The low-voltage curves for CSL 2, CSL 3, and CSL 4 were created by using their respective CSL 2, CSL 3, and CSL 4 basic-voltage efficiency curves, and altering all equation parameters by the difference in the coefficients between the CSL 1 basic-voltage and low-voltage equations. This approach had the effect of shifting the CSL 2, CSL 3, and CSL 4 low-voltage curves downward from their corresponding basic-voltage CSL 2, CSL 3, and CSL 4 curves, by a similar amount as the shift seen in the ENERGY STAR 2.0 equations. Today's amended standards for product classes C, D, and E were established using this methodology.

Eastman Kodak commented that the no-load equations should be a continuous function of output power for EPSs with nameplate output powers less than 250 watts. (Eastman Kodak, No. 125 at p. 2) However, as explained, DOE's approach is consistent with the EISA 2007 standards and the former ENERGY STAR 2.0 program for EPSs. In both cases, the no-load power requirement is a step function based on

the power output of the EPS. Using that assumption, DOE conducted an engineering analysis and found no strong correlation between no-load power and output power that would warrant deviating from the analytical structure of these programs. The equations for no-load power and active-mode efficiency formed the foundation of DOE's standards analysis, and the approach has been largely supported by stakeholders throughout the course of the rulemaking. Therefore, DOE maintained its step function equations for no-load power in amending the standards for EPSs in today's final rule.

After applying the approach described above and analyzing the products at issue, DOE believes that the ENERGY STAR 2.0 low-voltage standard equation for AC–DC conversion is an appropriate standard for multiple-voltage EPSs because lower power EPSs tend to be less efficient. DOE took into account that fact and has created an equation that scales with output power, should any low-power multiple-voltage EPSs enter the market in the future. As detailed in chapter 5 of the TSD, the ENERGY STAR 2.0 low-voltage equation matches the CSL equation DOE is adopting for the multiple-voltage EPS standard at the representative unit's output power of 203 watts, but also sets less stringent efficiency standards for lower power EPSs. DOE applied the same constraints when fitting the equation to the test data as it did for product classes B, C, D, and E. DOE received no comments on this approach in setting a standard for multiple-voltage EPSs.

For product class H (high-power EPSs), DOE set a discrete standard for all EPSs greater than 250 watts. DOE believes this is appropriate for two main reasons: (1) DOE is aware of only one application for high-power EPSs (amateur radios) and (2) this approach is consistent with the standard for product class B, which is a discrete level for all EPSs with nameplate output powers greater than 49 watts. In light of these facts, setting a single efficiency level as the standard for all EPSs with output power greater than 250 watts (high-power EPSs) appears to be a reasonable approach to ensure a minimal level of energy efficiency while minimizing the overall level of burden on manufacturers. DOE received no comments on this approach in setting a standard for high power EPSs.

6. Proposed Standards

a. Product Classes B, C, D, and E

In the NOPR, DOE proposed standard levels for all the product classes that were analyzed as part of the EPS engineering analysis. For product classes B, C, D, and E, which contained Class A, medical, and some MADB EPSs broken out by type of power conversion and nameplate output voltage, DOE proposed CSL 3, or the best-in-market CSL. To develop the proposed standard level, DOE "curve fit" an equation to test results of the most efficient EPSs it could find on the market at each representative output power.[23] DOE announced its intention to designate the proposed level "Level VI" in a revised and updated version of the International Efficiency Marking Protocol for EPSs. DOE received many comments on the proposed standard levels for product classes B, C, D, and E.

Panasonic, Cobra Electronics, ITI, Salcomp, Duracell, the Republic of Korea, and Eastman Kodak all commented that DOE should forgo setting an EPS standard at level VI and adopt the current level V requirement as the Federal standard to harmonize with the E.U. and other international efficiency programs. (Panasonic, No. 120 at p. 2; Cobra Electronics, No. 130 at p. 8; ITI, No. 131 at p. 4, Salcomp, No. 73 at p. 2; Duracell, No. 109 at p. 4; Republic of Korea, No. 148 at p. 1; Eastman Kodak, No. 125 at p. 2) ITI stated that DOE's proposed standard "breaks away from global harmonization efforts and would require significant industry-wide redesign," and called it "unjustifiable." (ITI, No. 131 at p. 4) AHAM also supported harmonization efforts and asserted that level V is "the most stringent level that is technologically feasible." (AHAM, No. 124 at p. 7) These statements were supported by Philips, which suggested that DOE should adopt Level V, which is known to be technologically feasible, and contemplate higher levels in a later rule. (Philips, No. 128 at p. 3) ITI also suggested such a phased approach, in which DOE would first adopt a standard at Level V for Class A EPSs and later investigate mandatory or voluntary standards for non-Class A EPSs. (ITI, No. 131 at p. 5) Nokia claimed that the DOE standards proposal "lacks sufficient economic justification to warrant such swift and demanding changes." (Nokia, No. 132 at p. 2) For all the reasons suggested by other stakeholders, the CEA noted that "further analysis is needed before DOE promulgates an amended energy conservation standard for Class A external power supplies." (CEA, No. 106 at p. 5)

[23] The term "curve fit" refers to generating an equation based on a set of data in order to describe the information mathematically.

Some interested parties made specific comments about the no-load power equation of the proposed standard. Flextronics claimed that with a compliance date two years from the publication of today's final rule, DOE should decrease the no-load power proposal from 100mW to 50mW for EPSs for mobile phones. (Flextronics, No. 145 at p. 1) Conversely, Logitech argued that they had just undergone costly design improvements to meet the no-load power requirement for the former ENERGY STAR program for EPSs and the E.U., which is 300 mW. (Logitech, No. 157 at p. 1)

DOE received support from energy efficiency advocates in favor of the standards proposed in the NOPR. NEEP noted that DOE's proposal represents a strong push toward rapidly increasing the energy efficiency of EPSs. (NEEP, No. 160 at p. 2) ARRIS Group also supported DOE's conclusion that "changing to a code V energy efficiency requirement will have little to no material cost impact since the majority of EPS products already comply." (ARRIS Group, No. 105 at p. 1)

In any efficiency standards rulemaking, DOE seeks to identify the most stringent standard that is economically justified and technically feasible. In the NOPR for EPSs, DOE proposed to amend the EISA 2007 regulations and increase the minimum efficiency standards to the best-in-market levels identified in the engineering analysis.

The comments submitted by manufacturers suggest that DOE has overestimated the capabilities of EPSs and that it should propose Level V as the federal standard (or equivalently to harmonize with the EU standards). The most recent EPS standards in the E.U. came into effect in 2011 and are equal to the Level V efficiency standard. However, more recent E.U. documents on EPS standards indicate a proposal to revise those standards to match the levels proposed by DOE in the NOPR by 2017 for the no-load, 25%, 50%, 75%, and 100% loading scenarios. The E.U. is also considering an additional 10% loading requirement outside the average efficiency metric from the other four loading conditions.[24] Other standards for EPSs outside the United States, including those in Canada and New Zealand, have set less stringent standards equal to the EISA 2007 level

[24] "Review Study on Commission Regulation (EC) No. 278/2009 External Power Supplies: Draft Final Report." March 13, 2012. Prepared for European Commission—Directorate-General for Energy. *http://www.powerint.com/sites/default/files/greenroom/docs/EPSReviewStudy_DraftFinalReport.pdf.*

(level IV). In addition, the E.U. instituted standby power consumption standards in 2010 and will revise those standards effective 2013. DOE notes that current international efficiency standards for EPSs are not all harmonized around efficiency level V, but it is possible that efficiency standards in the U.S. and E.U. may harmonize around the standards announced in today's final rule within the next several years. For more detail, see section IV.G.3 below and chapter 9 of the TSD.

As stakeholders have said, and as is shown in DOE's engineering analysis, the majority of EPSs already meet or exceed the Level V requirements so, in addition to the most recent E.U. standards, the incremental cost to manufacturers to achieve this level is nearly zero and any additional energy savings beyond today's market would be negligible. (ARRIS Group, No. 105 at p. 1). The DOE analysis of EPS shipments projects a base case assumption of the efficiency of EPSs that would be shipped in the future if DOE did not issue today's final rule. DOE only accounts for the energy savings and incremental costs that occur between this base case projection and the standards case that results from issuing today's final rule. In the base case projection, DOE presumes that 69% of all EPSs sold in the United States in 2015 would meet or exceed Level V, while 31% would only meet the Level IV requirements. This assumption is equal to the shipments-weighted average distribution for product classes B, C, D, and E, and is based on test results from the engineering analysis and assumptions about increases in product efficiency that would occur as a result of the ENERGY STAR program and mandatory standards in the European Union. Chapters 3 and 9 of the TSD describe DOE's efficiency distribution assumptions in greater detail. While DOE believes the baseline efficiency levels used in today's final rule are justified, DOE conducted an additional sensitivity analysis using different assumptions about the base case efficiency of EPSs that will be on the market in 2015. The results of this sensitivity analysis, presented in Appendix 10–A of the TSD, depict the national economic and energy impacts that would occur under alternative scenarios.

Commenters also claimed, without providing any supporting data, that any standard that is more stringent than Level V is technically infeasible and economically unjustifiable despite DOE's detailed analysis. The proposal put forth by DOE in the NOPR clearly points out that the selected standard level can be supported by products on the market and is not "technically infeasible". DOE outlines its complete analysis of the current EPS market as well as pathways to higher efficiencies based on information gathered from manufacturers and independent consultants in chapter 5 of the TSD to today's final rule.

Concerning the no-load mode proposal, DOE created matched pairings of efficiency and no-load power for all representative units, as discussed in section IV.C.2. Under that structure, any standard would match a continuous active-mode efficiency equation with a no-load step function. While DOE's analysis shows that 50 mW is technically achievable, which is equivalent to Flextronic's recommendation, it is only achievable for lower power EPSs (*e.g.*, those for cell phones), and would not be applicable as a flat standard for all EPSs as outlined in Chapter 5 of the TSD. Therefore, in today's final rule, DOE is not adopting a no-load power requirement that is flat and equivalent to 50 mW across all nameplate output powers and instead is adopting a step function equation that sets a specific no-load power limit for EPSs based on output power.

DOE is not adopting a standard for either average active-mode efficiency or no-load power consumption for EPSs in product class C–1 in today's final rule. DOE believes the low-voltage high-current output inherent in the design of these products limits their achievable efficiencies due to input rectification voltage drops relative to the output voltage, resistive losses in the higher current outputs, and the potential to decrease the utility of these products to improve efficiency by forcing manufacturers to utilize more expensive and larger components to meet the proposed standards.

NRDC commented that indirect operation EPSs should be subject to the same standards as direct operation EPSs, citing a lack of technical differences between the two groups of products. NRDC asserted that the proposed battery charger standards, if adopted, might be insufficient to increase the efficiency of indirect operation EPSs to the levels shown in the EPS standards analysis to be cost-effective. NRDC also expressed concern that because there is no obvious way to visually distinguish between direct and indirect operation EPSs, a manufacturer could circumvent standards by misrepresenting a direct operation EPS as an indirect operation EPS. (NRDC, No. 114 at p. 16) The California IOUs concurred with NRDC's comments. (CA IOUs, No. 138 at p. 20)

DOE continues to believe that a distinction between indirect and direct operation EPSs is justified. DOE recognizes that some wall adapters that are part of battery charging systems serve a different purpose than "regular" EPSs, have different design constraints, and should be regulated differently from each other.

In the determination analysis and in the standards preliminary analysis, the characteristic that distinguished this group of devices was the presence of "charge control." (Non-Class A EPS Determination Final Rule, 75 FR 27170, May 14, 2010; Preliminary Analysis TSD, No. 31 at p. 78, September 2010) DOE concluded from this analysis that standards would be warranted for non-Class A EPSs based in part on its understanding that devices with charge control were outside the scope of analysis because they were intended to charge batteries and therefore not considered EPSs. This understanding carried over into the analyses conducted as part of the present standards rulemaking.

This general approach has received support from manufacturers and utilities throughout the rulemaking process. For example, AHAM, PTI, and Wahl Clipper commented in response to the preliminary analysis that MADB wall adapters should be regulated as battery charger components, but not as EPSs. (AHAM, No. 42 at pp. 2, 3, 13; PTI, No. 45 at p. 4; Wahl Clipper, No. 53 at p. 1) Similarly, PG&E, two other energy utilities, and five efficiency advocates submitted a joint comment expressing their support for requiring wall adapters that perform charge control functions to be regulated as battery charger components, but not as EPSs. (PG&E, *et al.*, No. 47 at pp. 3–4) In the March 2012 NOPR, DOE maintained this approach but altered the specific criteria for differentiating between the two types of devices by proposing that those EPSs that cannot operate an end-use product directly would not be subject to the proposed standards. DOE continues to believe that it would be inappropriate to require indirect operation EPSs to meet the new and amended standards being adopted today.

DOE notes that battery charger standards will be handled separately from EPSs. And while NRDC asserts that DOE's proposed standards for battery chargers would not compel manufacturers to increase the efficiency of indirect operation EPSs, any battery charger standards DOE may adopt would need to achieve the maximum

improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) These standards would be evaluated based on the expected improvements in the energy efficiency of battery chargers, not of the EPSs—for which Congress has created a separate regulatory scheme. Manufacturers would have the flexibility to decide how to modify their products to achieve the improvements in energy efficiency necessitated by any battery charger standard DOE might adopt. The available choices could include using more efficient EPSs or other alternative design paths.

As for NRDC's concern that manufacturers might mistakenly or intentionally misrepresent direct operation EPSs as indirect operation EPSs and circumvent any applicable standards, DOE notes that it has created a regulatory framework for EPSs that meet statutory requirements while minimizing complexity. To that end, DOE developed a straightforward method (discussed above) for identifying indirect operation EPSs. DOE believes it has developed a method that is simple enough that any manufacturer can use it to determine whether a given EPS is an indirect operation EPS. Furthermore, Class A indirect operation EPSs continue to be required to meet the standards in EISA 2007 established by Congress.

b. Product Class X

DOE proposed adopting the ENERGY STAR specification for low-voltage EPSs as its standard for multiple-voltage EPSs. In DOE's view, this standard would be economically justified because DOE's analysis indicated that the standard would provide the greatest accumulation of net social benefits for the one product DOE analyzed in product class X (see section V.C.1.b of the NOPR). The equation on which this standard was based provided a means to apply the standard using a continuous function of output power that would readily enable a manufacturer to determine what efficiency level it would need to meet for any future multiple-voltage products that might be produced. DOE sought comment on this proposal from interested parties.

Microsoft commented that DOE's proposed standard for multiple-voltage EPSs does not yield results that are comparable or representative of actual use citing the fact that the game console EPS that would be required to meet the proposed standard is most efficient between the loading points it operates in most frequently, roughly between 46 and 63 percent load. Microsoft believes that because DOE's test procedure requires averaging the efficiency over multiple loading points beyond that range, the procedure would not accurately capture real world efficiency and energy savings potential of its game console EPS. (Microsoft, No. 110 at p. 2) The CEA agreed, stating that the "standard for multiple-voltage EPSs is inappropriate for the one product impacted by it." (CEA, No. 106 at p. 6) NRDC suggested that, in lieu of DOE's proposed standard, multiple-voltage EPSs should be required to meet only the efficiency level of their lowest output voltage. (NRDC, No. 114 at p. 14)

In the case of multiple-voltage EPSs, DOE's intent was to propose a continuous standard as a function of output power similar to the single-voltage EPS proposal. While only one product currently falls into this class, this situation may not always be the case. To account for the possibility of additional types of multiple-voltage EPSs becoming commercially available, DOE proposed using an average efficiency metric over the four loading conditions identified in the multiple-voltage test procedure. Using the current methodology, any future products that are sold with multiple-voltage EPSs will have a universal test method and set of measurable efficiency metrics to evaluate against the new federal standard.

Adopting the NRDC approach (i.e. setting requirements only on the lowest output voltage) would not ensure that the lowest voltage bus would provide any significant power to the end-use product in a real-world application. Consequently, the overall efficiency of the EPS could be far less than testing would indicate. In such a situation, a highly efficient lower voltage output would have a negligible impact on the overall system efficiency should the higher voltage output provide significantly more power to the end-use consumer product. For instance, the low-voltage output on the EPS in question provides only 2.5 percent of the overall system power at full load. While the output may be highly efficient, its overall impact on the system is minimal and using NRDC's method would not allow DOE to properly capture the additional energy usage of the EPS.

Manufacturers of multiple-voltage EPSs could also take advantage of such a loophole by designing a highly efficient low-voltage output despite its contribution, or lack thereof, to the overall energy consumption of the EPS while paying little attention to the higher voltage output(s). There are several ways manufacturers can design multiple output EPSs (i.e. multiple transformer taps, separate filter stages, paralleling several outputs of a single voltage) and there is no guarantee that improving one output bus would result in improvements to any other outputs. In any case where DOE does not measure all outputs, the reported energy consumption of the EPS (based on NRDC's approach) would not be an accurate representation of how much energy a given device would use. In light of the potential for this problematic result, DOE is opting to adopt its proposed approach to ensure (1) the universal applicability of its procedure and the standard and (2) reasonably accurate measurements of energy efficiency for these products.

c. Product Class H

To develop the efficiency standard level proposed in the NOPR for product class H (high power) EPSs, DOE scaled the CSLs from the 120W representative unit to the 345W representative unit in the high power product class. Like the proposed standards for the other EPS product classes, DOE chose the most stringent level that was technologically feasible and economically justified. DOE sought comment on the methodology for selecting a standard for high power EPSs, and received only one comment.

NRDC recommended that "DOE set the same efficiency levels for class H as for class B instead of the current proposal of 87.5%." (NRDC, No. 114 at p. 14) However, like multiple-voltage EPSs, there is only one product (amateur radios) that DOE could identify that uses high power EPSs. The 120W products in product class B have a representative nameplate output voltage of 19 volts while the high power EPSs in product class H have a representative nameplate output voltage of 13 volts. While the EPSs in product class B do not have higher nameplate output powers than 250 watts, the high power product class H covers all EPSs above 250 watts. In comparing the 120 watt unit at 19 volts to the 345 watt unit at 13 volts, DOE found that the high power EPSs have much higher output currents since the nameplate output power (i.e. watts) is the product of nameplate output current and nameplate output voltage. Higher output currents create greater resistive losses associated with the output cord and secondary side filtering. When scaling the 120W results to the 345W representative unit, DOE adjusted for this disparity using the voltage scaling techniques it developed during its EPS testing, as detailed in chapter 5 of the TSD, and ultimately proposed an efficiency standard slightly lower than

the direct operation EPSs below 250W nameplate output power. This technical limitation on the achievable efficiency remains and the standards adopted in today's final rule accounts for this limitation.

D. Markups Analysis

The markups analysis develops appropriate markups in the distribution chain to convert the MSP estimates derived in the engineering analysis to consumer prices. At each step in the distribution chain, companies mark up the price of the product to cover business costs and profit margin. Given the variety of products that use EPSs, distribution varies depending on the product class and application. As such, DOE assumed that the dominant path to market establishes the retail price and, thus, the markup for a given application. The markups applied to end-use products that use EPSs are approximations of the EPS markups.

In the case of EPSs, the dominant path to market typically involves an end-use product manufacturer (i.e. OEM) and retailer. DOE developed OEM and retailer markups by examining annual financial filings, such as Securities and Exchange Commission (SEC) 10–K reports, from more than 80 publicly traded OEMs, retailers, and distributors engaged in the manufacturing and/or sales of consumer applications that use EPSs.

DOE typically calculates two markups for each product in the markups analysis. These are: a markup applied to the baseline component of a product's cost (referred to as a baseline markup) and a markup applied to the incremental cost increase that results from standards (referred to as an incremental markup). The incremental markup relates the change in the MSP of higher-efficiency models (the incremental cost increase) to the change in the retailer's selling price.

Commenting on retail markups, Phillips, Schumacher, and Wahl Clipper stated that the concept of margins is very significant to retailers, and it is not realistic to predict that retailers voluntarily will act in a way that reduces their margins. (Philips, No. 128 at p. 6; Schumacher, No. 182 at p. 6; Wahl Clipper, No 153 at p. 2) Motorola commented that retailers will not be willing to lower their markups because product efficiency has increased. (Motorola Mobility, No. 121 at p. 4) In contrast, PTI stated that DOE's estimates of markups are sufficient for the purposes of the analysis. (PTI, No. 133 at p. 6)

DOE recognizes that retailers may seek to preserve margins. However, DOE's approach assumes that appliance retail markets are reasonably competitive, so that an increase in the manufacturing cost of appliances is not likely to contribute to a proportionate rise in retail profits, as would be expected to happen if markups remained constant. DOE's methodology for estimating markups is based on a mix of economic theory, consultation with industry experts, and data from appliance retailers.[25] In conducting research, DOE has found that empirical evidence is lacking with respect to appliance retailer markup practices when a product increases in cost (due to increased efficiency or other factors). DOE understands that real-world retailer markup practices vary depending on market conditions and on the magnitude of the change in cost of goods sold (CGS) associated with an increase in appliance efficiency. DOE acknowledges that detailed information on actual retail practices would be helpful in evaluating change in markups on products after appliance standards take effect. For this rulemaking, DOE requested data from stakeholders in support of alternative approaches to markups, as well as any data that shed light on actual practices by retailers; however, no such data was provided. Thus, DOE continues to use an approach that is consistent with economic theory of firm behavior in competitive markets.

Chapter 6 of the TSD provides additional detail on the markups analysis.

E. Energy Use Analysis

The energy use analysis provides estimates of the annual energy consumption of EPSs at the considered efficiency levels. DOE uses these values in the LCC and PBP analyses and in the NIA. DOE estimated the annual energy use of EPSs in the field as they are used by consumers.

EPSs are power conversion devices that transform input voltage to a suitable voltage for the end-use application they are powering. A portion of the energy that flows into an EPS flows out to an end-use product and, thus, cannot be considered to be consumed by the EPS. However, to provide the necessary output power, other factors contribute to EPS energy consumption, *e.g.*, internal losses and overhead circuitry.[26] Therefore, the traditional method for calculating energy consumption—by measuring the energy a product draws from mains while performing its intended function(s)—is not appropriate for EPSs because that method would not factor in the energy delivered by the EPS to the end-use application, and thus would overstate EPS energy consumption. Instead, DOE considered energy consumption to be the energy dissipated by the EPS (losses) and not delivered to the end-use product as a more accurate means to determine the energy consumption of these products. Once the energy and power requirements of those end-use products were determined, DOE considered them fixed, and DOE focused its analysis on how standards would affect the energy consumption of EPSs themselves.

Applying a single usage profile to each application, DOE calculated the unit energy consumption for EPSs. In addition, DOE examined the usage profiles of multiple user types for applications where usage varies widely (for example, a light user and a heavy user or an amateur user and professional user). By examining these usage profiles DOE provided stakeholders with greater transparency in its energy consumption calculation, such that they could provide specific comments where DOE's estimates were incorrect.

AHAM voiced support for the usage profiles presented by DOE in the NOPR. While AHAM commented that DOE could more accurately capture the usage of infrequently used product classes, it largely supported DOE's efforts to consider the variation in usage for EPSs. AHAM recommended that DOE reevaluate these usage profiles in the future to more accurately quantify the usage profiles for infrequently charged products. (AHAM, No. 124 at p. 7) No other feedback was received on this issue. In light of the support expressed for its approach, and for the technical reasons explained above, DOE continued to apply the same approach.

With respect to the various loading points DOE used to estimate energy usage, NRDC commented that DOE overestimated its loading point assumption for laptop computer EPSs in the "operating" application state, which, given the reduced EPS efficiency at lower loading point levels, would lead to an understatement of energy

[25] An extensive discussion of the methodology and justification behind DOE's general approach to markups calculation is presented in Larry Dale, et al. 2004. "An Analysis of Price Determination and Markups in the Air-Conditioning and Heating Equipment Industry." LBNL–52791. Available for download at *http://eetd.lbl.gav/sites/all/files/an_analysis_af_price_determiniation_and_markups_in_the_air_conditianing_and_heating_equipment_industry_lbnl-52791.pdf.*

[26] Internal losses are energy losses that occur during the power conversion process. Overhead circuitry refers to circuits and other components of the EPS, such as monitoring circuits, logic circuits, and LED indicator lights, that consume power but do not directly contribute power to the end-use application.

losses. (These EPSs fall in product class B.) NRDC pointed to a recent EPA dataset underlying the ENERGY STAR v6.0 Computer Specification Revision [27] that showed loading points for a comparable application state of approximately 10–20% for most products. This loading point range, however, differs from DOE's test data, which showed the "operating" loading point to be at 28%. (NRDC, No. 114 at p. 18)

To address this comment, DOE worked with the EPA to better understand the data that it used to estimate the loading point. DOE learned that EPA's estimate was based on a separate set of empirical data from Ecma International (formerly the European Computer Manufacturers Association) in which measurements were taken from 17 notebook computers operating in real-world scenarios. DOE analyzed these data and found that idle loading points were approximately 30%, an estimate that is very much in line with DOE's estimated loading point of 28%. Therefore, in developing the final standards, DOE relied on the loading points presented in the NOPR.

DOE also explored high- and low-savings scenarios in an LCC sensitivity analysis. As part of the sensitivity analysis, DOE considered alternate usage profiles and loading points to account for uncertainty in the average usage profiles and explore the effect that usage variations might have on energy consumption, life-cycle cost, and payback. Additional information on this sensitivity analysis is contained in appendix 8B to the TSD.

[27] *https://www.energystar.gov/products/specs/node/143* (last accessed October 23, 2012).

DOE does not assume the existence of a rebound effect, in which consumers would increase use in response to an increase in energy efficiency and resulting decrease in operating costs. For EPSs, DOE expects that, in light of the small amount of savings expected to flow to each individual consumer over the course of the year, the rebound effect is likely to be negligible because consumers are unlikely to be aware of the efficiency improvements or notice the decrease in operating costs that would result from new standards for these products. DOE analyzed the impacts on individual consumers in its Life-Cycle Cost and Payback Period Analyses described below.

F. Life-Cycle Cost and Payback Period Analyses

This section describes the LCC and payback period analyses and the spreadsheet model DOE used for analyzing the economic impacts of possible standards on individual consumers. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 and appendix 8A of the TSD. DOE conducted the LCC and PBP analyses using a spreadsheet model developed in Microsoft Excel. When combined with Crystal Ball (a commercially-available software program), the LCC and PBP model generates a Monte Carlo simulation [28] to perform the analysis by incorporating uncertainty and variability considerations.

[28] Monte Carlo simulations model uncertainty by utilizing probability distributions instead of single values for certain inputs and variables.

The LCC analysis estimates the impact of a standard on consumers by calculating the net cost of an EPS under a base-case scenario (in which no new energy conservation standard is in effect) and under a standards-case scenario (in which the proposed energy conservation standard is applied). The base-case scenario is determined by the efficiency level that a sampled consumer currently purchases, which may be above the baseline efficiency level. The life-cycle cost of a particular EPS is composed of the total installed cost (which includes manufacturer selling price, distribution chain markups, sales taxes, and any installation cost), operating expenses (energy and any maintenance costs), product lifetime, and discount rate. As noted in the NOPR, DOE considers installation costs to be zero for EPSs.

The payback period is the change in purchase expense due to a more stringent energy conservation standard, divided by the change in annual operating cost that results from the standard. Stated more simply, the payback period is the time period it takes to recoup the increased purchase cost of a more-efficient product through energy savings. DOE expresses this period in years.

Table IV–11 summarizes the approach and data that DOE used to derive the inputs to the LCC and PBP calculations for the NOPR and the changes made for today's final rule. The following sections discuss these inputs and comments DOE received regarding its presentation of the LCC and PBP analyses in the NOPR, as well as DOE's responses thereto.

Table IV-11 Summary of Inputs and Key Assumptions Used in the NOPR LCC Analyses and Final Rule LCC Analysis

Inputs	March 2012 NOPR	Changes from the Proposed Rule for the Final Rule
Manufacturer Selling Price	Derived from the Engineering Analysis through manufacturer interviews and test/teardown results.	Updated the manufacturer selling price for the 60 watt unit based on the most recent manufacturer data.
Markups	Considered various distribution channel pathways for different applications. Applied a reduced "incremental" markup to the portion of the product price exceeding the baseline price. See Chapter 6 for details.	No Change.
Sales Tax	Derived weighted-average tax values for each Census division and large State from data provided by the Sales Tax Clearinghouse.[1]	Updated the sales tax using the latest information from the Sales Tax Clearinghouse.[2]
Installation Cost	Assumed to be zero.	No change.
Maintenance Cost	Assumed to be zero.	No change.
Unit Energy Consumption	Determined for each application based on estimated loading points and usage profiles.	No Change.
Electricity Prices	Price: Based on EIA's 2008 Form EIA-861 data.[3] Variability: Regional energy prices determined for 13 regions. DOE also considered subgroup analyses using electricity prices for low-income consumers and top tier marginal price consumers.	Updated to EIA's 2011 Form EIA-861 data.[4]
Electricity Price Trends	Forecasted with EIA's Annual Energy Outlook 2010.[5]	Updated with EIA's Annual Energy Outlook 2013.[6]
Lifetime	Determined for each application based on multiple data sources. See chapter 3 of the TSD for details.	No Change.
Discount Rate	Residential: Approach based on the finance cost of raising funds to purchase and operate EPSs either through the financial cost of any debt incurred (based on the Federal Reserve's Survey of Consumer Finances data[7] for 1989, 1992, 1995, 1998, 2001, 2004, and 2007) or the opportunity cost of any equity used. Time-series data was based on geometric means from 1980-2009. Commercial: Derived discount rates using the cost of capital of publicly-traded firms based on data from Damodaran Online,[8] the Value Line Investment survey,[9] and the Office of Management and Budget (OMB) Circular No. A-94.[10] DOE used a 40-year average return on 10-year treasury notes to derive the risk-free rate. DOE updated the equity risk premium to use the geometric average return on the S&P 500 over a 40-year time period.	Residential: DOE updated the calculations to consider the geometric means for all time-series data from 1982-2011. DOE added data from the Federal Reserve's Survey of Consumer Finances for 2010. Commercial: DOE updated all sources to the most recent version (Damodaran Online,[8] the Value Line Investment survey,[9] and the Office of Management and Budget (OMB) Circular No. A-94).
Sectors Analyzed	All reference case results represent a weighted average of the residential and commercial sectors.	No Change.
Base Case Market Efficiency Distribution	Where possible, DOE derived market efficiency distributions for specific applications within a representative unit or product class.	No Change.

[1] The four large States are New York, California, Texas, and Florida.

[2] Sales Tax Clearinghouse, Aggregate State Tax Rates. Available at: https://thestc.com/STRates.stm.

[3] U.S. Department of Energy. Energy Information Administration. Form EIA-861 Final Data File for 2008. November 2010. Washington, D.C. Available at: http://www.eia.doe.gov/cneaf/electricity/page/eia861.html.
[4] U.S. Department of Energy. Energy Information Administration. Form EIA-861 Final Data File for 2011. September 2012. Washington, D.C. Available at: http://www.eia.doe.gov/cneaf/electricity/page/eia861.html.
[5] U.S. Department of Energy. Energy Information Administration. Annual Energy Outlook 2010. November 2010. Washington, D.C. Available at: http://www.eia.gov/forecasts/aeo/er/index.cfm.
[6] U.S. Department of Energy. Energy Information Administration. Annual Energy Outlook 2013. June 2013. Washington, D.C. Available at: http://www.eia.gov/forecasts/aeo/er/index.cfm.
[7] The Federal Reserve Board, Survey of Consumer Finances 1989, 1992, 1995, 1998, 2001, 2004, 2007, 2010. Available at: http://www.federalreserve.gov/pubs/oss/oss2/scfindex.html.
[8] Damodaran Online Data Page, Historical Returns on Stocks, Bonds and Bills-United States, 2010. Damodaran. Available at: http://pages.stern.nyu.edu/~adamodar.
[9] Value Line. Value Line Investment Survey. 2010. Available at: http://www.valueline.com.
[10] U.S. Office of Management and Budget. Circular No. A-94. Appendix C. 2009. Available at: http://www.whitehouse.gov/omb/circulars_a094_a94_appx-c/.
[11] The Federal Reserve Board, Federal Reserve Statistical Release, Selected Interest Rates, Historical Data, Instrument: Treasury Constant Maturities, Maturity: 10-year, Frequency: Annual, Description: Market yield on U.S. Treasury securities at 10-year constant maturity, quoted on investment basis. Available at: http://www.federalreserve.gov/releases/H15/data.htm.

1. Manufacturer Selling Price

In the preliminary analysis, DOE used a combination of test and teardown results and manufacturer interview results to develop manufacturer selling prices. For the final rule, DOE maintained the manufacturer selling prices used in the NOPR analysis, with the exception of the 60-Watt representative unit, as discussed in section IV.C. Further detail on the MSPs can be found in chapter 5 of the TSD.

Examination of historical price data for a number of appliances that have been subject to energy conservation standards indicates that an assumption of constant real prices and costs may overestimate long-term trends in appliance prices. Economic literature and historical data suggest that the real costs of these products may in fact trend downward over time according to "learning" or "experience" curves. On February 22, 2011, DOE published a Notice of Data Availability (NODA, 76 FR 9696) stating that DOE may consider improving regulatory analysis by addressing equipment price trends. In the NODA, DOE proposed that when sufficiently long-term data are available on the cost or price trends for a given product, it would analyze the available data to forecast future trends.

To forecast a price trend for the NOPR, DOE considered the experience curve approach, in which an experience rate parameter is derived using two historical data series on price and cumulative production, but in the absence of historical data on shipments of EPSs and of sufficient historical Producer Price Index (PPI) data for small electrical appliance manufacturing from the Bureau of Labor Statistics (BLS),[29] DOE could not use this approach. This situation is partially due to the nature of EPS design. EPSs are made up of many electrical components whose size, cost, and performance rapidly change, which leads to relatively short design lifetimes. DOE also considered performing an exponential fit on the deflated AEO's Projected Price Indexes that most narrowly include EPSs. However, DOE believes that these indexes are too broad to accurately capture the trend for EPSs. Furthermore, EPSs are not typical consumer products; they are more like a commodity that OEMs purchase.

Given the uncertainty, DOE did not incorporate product price changes into the NOPR analysis and is not including them in today's final rule. For the NIA, DOE also analyzed the sensitivity of results to two alternative EPS price forecasts. Appendix 10–B of the NOPR TSD describes the derivation of alternative price forecasts.

2. Markups

DOE applies a series of markups to the MSP to account for the various distribution chain markups applied to the analyzed product. These markups are evaluated for each application individually, depending on its path to market. Additionally, DOE splits its markups into "baseline" and "incremental" markups. The baseline markup is applied to the entire MSP of the baseline product. The incremental markups are then applied to the marginal increase in MSP over the baseline's MSP. The approach used for markups in the NOPR was maintained for the final rule. Further detail on the markups can be found in section IV.D above and in chapter 6 of the TSD.

3. Sales Tax

As in the NOPR, DOE obtained State and local sales tax data from the Sales Tax Clearinghouse for the final rule. The data represented weighted averages that include county and city rates. DOE used the data to compute population-weighted average tax values for each Census division and four large States (New York, California, Texas, and Florida). For the final rule, DOE retained this methodology and used updated sales tax data from the Sales Tax Clearinghouse.[30] DOE also obtained up-to-date population estimates from the U.S. Census Bureau for today's final rule.[31]

4. Installation Cost

As detailed in the NOPR, DOE considered installation costs to be zero for EPSs because installation would typically entail a consumer simply unpacking the EPS from the box in which it was sold and connecting the device to mains power and its associated product. Because the cost of this "installation" (which may be considered temporary, as intermittently used devices might be unplugged for storage) is not quantifiable in dollar terms, DOE considered the installation cost to be zero.

[29] Series ID PCU33521–33521; *http://www.bls.gov/ppi/.*

[30] Sales Tax Clearinghouse, Aggregate State Tax Rates. *https://thestc.com/STRates.stm.*

[31] The U.S. Census Bureau. Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2000 to July 1, 2009 *http://www.census.gov/popest/data/state/totals/2009/tables/NST-EST2009-01.xls.*

In response to the NOPR, NEMA noted that no installation costs were accounted for in the LCC and PBP calculations. NEEA pointed out that the LCC focuses on incremental costs, rather than overall costs. It noted that it would be very difficult to find data supporting an installation cost that increases with increasing efficiency levels. (NEEA, Pub. Mtg. Transcript, No. 104 at p. 189) DOE agrees with the comments made by NEEA and has maintained zero installation costs for the final rule analysis.

5. Maintenance Cost

In the NOPR analysis, DOE did not consider repair or maintenance costs for EPSs. In making this decision, DOE recognized that the service life of an EPS typically exceeds that of the consumer product it powers. Furthermore, DOE noted that the cost to repair the EPS might exceed the initial purchase cost as these products are relatively low cost. Thus, DOE estimated that it would be extremely unlikely that a consumer would incur repair or maintenance costs for an EPS. Also, if an EPS failed, DOE expects that consumers would typically discard the EPS and purchase a replacement. DOE received no comments challenging this assumption and has continued relying on this assumption for purposes of calculating the final rule's potential costs and benefits.

6. Product Price Forecast

As noted in section IV.F.1, to derive its central estimates DOE assumed no change in EPS prices over the 2015–2044 period. In addition, DOE conducted a sensitivity analysis using two alternative price trends based on AEO indexes. These price trends, and the NPV results from the associated sensitivity cases, are described in appendix 10–B of the TSD.

7. Unit Energy Consumption

The final rule analysis uses the same approach for determining UECs as the one used in the NOPR. The UEC was determined for each application based on estimated loading points and usage profiles. Further detail on the UEC calculations can be found in section IV.E above and in chapter 7 of the TSD.

8. Electricity Prices

DOE determined energy prices by deriving regional average prices for 13 geographic areas consisting of the nine U.S. Census divisions, with four large states (New York, Florida, Texas, and California) treated separately. The derivation of prices was based on data in EIA's Form EIA–861. For the final rule, DOE updated to EIA's Form EIA–861 2011.

9. Electricity Price Trends

In the NOPR analysis, DOE used data from EIA's *Annual Energy Outlook (AEO) 2010* to project electricity prices to the end of the product lifetime.[32] For the final rule, DOE used the final release of the AEO 2013,[33] which contained reference, high- and low-economic-growth scenarios. DOE received no comments on the electricity price forecasts it used in its analyses.

10. Lifetime

For the NOPR analysis, DOE considered the lifetime of an EPS to be from the moment it is purchased for end-use up until the time when it is permanently retired from service. Because the typical EPS is purchased for use with a single associated application, DOE assumed that it would remain in service for as long as the application does. Even though many of the technology options to improve EPS efficiencies may result in an increased useful life for the EPS, the lifetime of the EPS is still directly tied to the lifetime of its associated application. With the exception of EPSs for mobile phones and smartphones (see below), the typical consumer will not continue to use an EPS once its application has been discarded. For this reason, DOE used the same lifetime estimate for the baseline and standard level designs of each application for the LCC and PBP analyses. DOE maintained this approach in the final rule analysis. Further detail on product lifetimes and how they relate to applications can be found in chapter 3 of the TSD.

The one exception to this approach (i.e. that EPSs do not exceed the lifetime of their associated end-use products) is the lifetime of EPSs for mobile phones and smartphones. While the typical length of a mobile phone contract is two years, and many phones are replaced and no longer used after two years, DOE assumed that the EPSs for these products will remain in use for an average of four years. This assumption is based on an expected standardization of the market around micro-USB plug technology, driven largely by the GSMA Universal Charging Solution.[34] However, Motorola Mobility commented that DOE incorrectly assumed that the mobile phone market is standardizing around a micro-USB plug. Motorola Mobility stated that as batteries increase in storage capacity, manufacturers may need to abandon micro-USB technology because of the limits it places on charge currents. (Motorola Mobility, No. 121 at p. 7)

To verify that this evolution towards micro-USB plug technology is in fact taking place, DOE examined more than 30 top-selling basic mobile phone and smartphone models offered online by Amazon.com, Sprint, Verizon Wireless, T-Mobile, and AT&T. DOE found that all of the newest smartphone models, other than the Apple iPhone, use micro-USB plug technology. DOE expects the micro-USB market to increase as more phones comply with the IEC 62684–2011. This standard mandates the use of common micro-USB chargers for all cellphones and is aimed at standardizing EPSs across all mobile phone manufacturers for the benefit of the consumer.

If new EPSs are compatible with a wide range of mobile phone and smartphone models, a consumer may continue to use the EPS from their old phone after upgrading to a new phone. Even though it is currently standard practice to receive a new EPS with a phone upgrade, DOE assumes that in the near future consumers will no longer expect manufacturers to include an EPS with each new phone.

For the NOPR analysis, DOE compared LCC results for each CSL for mobile and smartphones with a two-year lifetime, to those with a four-year lifetime. Assuming a lifetime of two (rather than four) years for mobile phone and smartphone EPSs resulted in lower life-cycle cost savings (or greater net costs) for consumers of those products. However, the net effect on Product Class B as a whole was negligible because mobile phones and smartphones together comprise only 7 percent of shipments in Product Class B. DOE did not receive any comments on this approach following the NOPR publication, and therefore retained the same lifetime approach used in the NOPR for the final rule analysis. LCC results for these and all other applications in Product Class B are shown in chapter 11 of the TSD.

DOE notes that the lifetime of the EPS is directly tied to the lifetime of its

[32] U.S. Department of Energy. Energy Information Administration. Annual Energy Outlook 2010. November, 2010. Washington, DC *http://www.eia.doe.gov/oiaf/aeo/.*

[33] U.S. Department of Energy. Energy Information Administration. Annual Energy Outlook 2013. June, 2013. Washington, DC *http://www.eia.doe.gov/oiaf/aeo/.*

[34] The GSMA Universal Charging Solution is an agreement between 17 mobile operators and manufacturers to have the majority of all new mobile phones support a universal charging connector by January 1, 2012. The press release for the agreement can be accessed here: *http://www.gsma.com/newsroom/mobile-industry-unites-to-drive-universal-charging-solution-for-mobile-phones/.*

associated application, even if many of the technology options to improve EPS efficiencies may result in a longer useful life for the EPS. The typical consumer will not use the EPS once the application has been discarded. For this reason, the baseline and standard level designs use the same lifetime estimate for the LCC and PBP analysis. See chapter 8 of the TSD for more details.

11. Discount Rate

In the NOPR analysis, DOE derived residential discount rates by identifying all possible debt or asset classes that might be used to purchase and operate products, including household assets that might be affected indirectly. DOE estimated the average shares of the various debt and equity classes in the average U.S. household equity and debt portfolios using data from the Survey of Consumer Finances (SCF) [35] from 1989 to 2007. DOE used the mean share of each class across the seven sample years as a basis for estimating the effective financing rate for products. DOE estimated interest or return rates associated with each type of equity and debt using SCF data and other sources. The mean real effective rate across the classes of household debt and equity, weighted by the shares of each class, is 5.1 percent.

For the commercial sector, DOE derived the discount rate from the cost of capital of publicly-traded firms falling in the categories of products that involve the purchase of EPSs. To obtain an average discount rate value for the commercial sector, DOE used the share of each category in total paid employees provided by the U.S. Census Bureau [36] and Federal,[37] State, and local [38] governments. By multiplying the discount rate for each category by its share of paid employees, DOE derived a commercial discount rate of 7.1 percent.

For the final rule, DOE used the same methodology as the preliminary analysis and NOPR with applicable updates to data sources. When deriving the residential discount rates, DOE added the 2010 Survey of Consumer Finances to their data set. For all time-series data, DOE evaluated rates over the 30-year time period of 1983–2012. The new discount rates were derived as 5.2 percent and 5.1 percent in the residential and commercial sectors, respectively. For further details on discount rates, see chapter 8 and appendix 8D of the TSD.

12. Sectors Analyzed

The NOPR analysis included an examination of a weighted average of the residential and commercial sectors as the reference case scenario. Additionally, all application inputs were specified as either residential or commercial sector data. Using these inputs, DOE then sampled each application based on its shipment weighting and used the appropriate residential or commercial inputs based on the sector of the sampled application. This approach provided more specificity as to the appropriate input values for each sector, and permitted an examination of the LCC results for a given representative unit or product class in total. DOE maintained this approach in the final rule. For further details on sectors analyzed, see chapter 8 of the TSD.

13. Base Case Market Efficiency Distribution

For purposes of conducting the LCC analysis, DOE analyzed candidate standard levels relative to a base case (*i.e.*, a case without new federal energy conservation standards). This analysis required an estimate of the distribution of product efficiencies in the base case (*i.e.*, what consumers would have purchased in 2015 in the absence of new federal standards). Rather than analyzing the impacts of a particular standard level assuming that all consumers will purchase products at the baseline efficiency level, DOE conducted the analysis by taking into account the breadth of product energy efficiencies that consumers are expected to purchase under the base case.

In preparing the NOPR analysis, DOE derived base case market efficiency distributions that were specific to each application where it had sufficient data to do so. This approach helped to ensure that the market distribution for applications with fewer shipments was not disproportionately skewed by the market distribution of the applications with the majority of shipments. As a result, the updated analysis more accurately accounted for LCC and PBP impacts. For today's final rule, DOE maintained the base case market efficiency distributions used in the NOPR analysis.

14. Compliance Date

The compliance date is the date when a new standard becomes operative, i.e., the date by which EPS manufacturers must manufacture products that comply with the standard. DOE calculated the LCC savings for all consumers as if each would purchase a new product in the year that manufacturers would be required to meet the new standard. DOE used a compliance date of 2013 in the analysis it prepared for its March 2012 NOPR and a compliance date of 2015 in the final rule analysis.

15. Payback Period Inputs

The PBP is the amount of time a consumer needs to recover the assumed additional costs of a more-efficient product through lower operating costs. As in the NOPR, DOE used a "simple" PBP for the final rule, because the PBP does not take into account other changes in operating expenses over time or the time value of money. As inputs to the PBP analysis, DOE used the incremental installed cost of the product to the consumer for each efficiency level, as well as the first-year annual operating costs for each efficiency level. The calculation requires the same inputs as the LCC, except for energy price trends and discount rates; only energy prices for the year the standard becomes required for compliance (2015 in this case) are needed.

DOE received multiple comments on its payback period analysis. ITI pointed out that the NOPR stated "a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year." (ITI, No. 131 at p. 6) ITI further noted that it was aware of preliminary cost-benefit analyses that indicate costs of the proposal exceeding the benefits to consumers by more than 10 times during the first year. Id. As ITI did not provide any data, DOE was unable to verify this claim.

Cobra Electronics also asserted that the projected energy savings would yield benefits for a minority of consumers and viewed the payback period as requiring that the price the consumer pays for a product will not increase more than three times what the value of the energy savings will be during the first year after its purchase. (Cobra Electronics, No. 130 at p. 7)

DOE notes that under 42 U.S.C. 6295(o)(2)(B)(iii), if the additional cost to the consumer of purchasing the product complying with an energy conservation standard level will be less

[35] *http://ww.federalreserve.gov/econresdata/scf/scfindex.htm.*

[36] U.S. Census Bureau. The 2010 Statistical Abstract. Table 607—Employment by Industry. *http://www.census.gov/compendia/statab/2010/tables/10s0607.xls.*

[37] U.S. Census Bureau. The 2010 Statistical Abstract. Table 484—Federal Civilian Employment and Annual Payroll by Branch. *http://www.census.gov/compendia/statab/2010/tables/10s0484.xls.*

[38] U.S. Census Bureau. Government Employment and Payroll. 2008 State and Local Government. *http://www2.census.gov/govs/apes/08stlall.xls.*

than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, there shall be a rebuttable presumption that such standard level is economically justified. In essence, the statute creates a presumption that a standard level satisfying this condition would be economically justified. It does not, however, indicate that the standard is necessarily economically justified if the payback period is under three years, nor does it indicate that the rebuttable presumption is the only methodology to show economic justification. DOE notes that it does not perform a stand-alone rebuttable presumption analysis, as it is already embodied in the LCC and PBP analysis. The rebuttable presumption is an alternative to the consideration of the seven factors set forth in 42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII) for establishing economic justification. The LCC and PBP analyses DOE conducted as part of the NOPR show that the standard levels proposed for EPSs in product class B are economically justified. Furthermore, DOE notes that in today's final rule, three out of four of the representative units for product class B have payback periods under three years, qualifying the adopted standard level for these representative units as economically justified under the rebuttable presumption. (The rebuttable presumption payback period is discussed further in section III.E.2 above, section V.B.1.c below, and in chapter 8 of the TSD.)

ARRIS Group also expressed concern over the payback periods presented in the NOPR. It noted that adjusting to a Level V baseline and averaging cost savings across all output powers would more than double the payback period to around 7 years, which would exceed the product's lifetime and provide no justified savings for the user. (ARRIS Group, No. 105 at p. 2)

As noted in section IV.A.1, level IV is the current federal standard, and therefore, units that meet level IV efficiency are currently permitted to be sold in the United States. While voluntary programs and efficiency standards outside the United States are driving the improvement of EPSs so that many EPSs sold in the United States meet level V, DOE has observed that EPSs that meet level IV currently exist in the marketplace. Therefore, as discussed in section C.6, DOE does not believe that adjusting the baseline assumption for all EPSs to level V would be appropriate. LCC savings estimates are weighted averages of the savings from improving efficiency from each efficiency level below the standard level up to the standard level. Thus, DOE's analysis accounts for the large percentage of units that would already be at level V in the absence of amended federal standards.

G. Shipments Analysis

Projections of product shipments are needed to predict the impacts standards will have on the Nation. DOE develops shipment projections based on an analysis of key market drivers for each considered product. In DOE's shipments model, shipments of products were calculated based on current shipments of product applications powered by EPSs. For the National Impact Analysis, DOE built an inventory model to track shipments over their lifetime to determine the vintage of units in the installed base for each year of the analysis period.

1. Shipment Growth Rate

In the NOPR, DOE noted that the market for EPSs had grown tremendously in the previous ten years. Additionally, DOE found that many market reports had predicted enormous future growth for the applications that employ EPSs. However, in projecting the size of these markets over the next 30-years, DOE considered the possibility that much of the market growth associated with EPSs had already occurred. In many reports predicting growth of applications that employ EPSs, DOE noted that growth was predicted for new applications, but older applications were generally not included. That is, EPS demand did not grow, but the products using these devices have transitioned to a new product mix. For example, during its initial market assessment, DOE identified mobile phones, digital cameras, personal digital assistants, and MP3 players as applications that use EPSs. However, in the past several years, the use of smart phones, which can function as all four of these individual applications, has accelerated, and these individual products may no longer be sold in large volumes in the near future. A quantitative example of this is shown in Table IV–12.

TABLE IV–12—EXAMPLE OF PRODUCT TRANSITION

Application	2007 Shipments	2008 Shipments	2009 Shipments
Smart Phones	19,500,000	28,555,000	41,163,000
Mobile Phones	101,500,000	102,775,000	94,239,000
Personal Digital Assistants	2,175,000	1,977,000	1,750,000
MP3 Players	48,020,000	43,731,000	40,101,000
Total	171,195,000	177,038,000	177,253,000

With this in mind, DOE based its shipments projections such that the per-capita consumption of EPSs will remain steady over time, and that the overall number of individual units that use EPSs will grow at the same rate as the U.S. population.

In the NOPR analysis, to estimate future market size while assuming no change in the per-capita EPS purchase rate, DOE used the projected population growth rate as the compound annual market growth rate. Population growth rate values were obtained from the U.S. Census Bureau 2009 National Projections, which forecast U.S. resident population through 2050. DOE took the average annual population growth rate, 0.75 percent, and applied this rate to all EPS product classes.

NRDC commented that EPS shipments had been growing significantly faster than the growth shown in the NOPR, driven in part by growth in consumer electronics and portable appliances over the previous few years. They attributed the slower shipment growth in 2009 and 2010 to the recession. By 2042, NRDC projected that annual shipments would grow to 1.3 billion units, 32% higher than DOE's projection of 1.0 billion units. (NRDC, No. 114 at p. 19) The California Investor-Owned Utilities also asserted that EPS stocks would grow faster than the population. These faster growth rates would increase the energy savings attributable to the standards. The CA IOU's stated that they supported the conclusions of NRDC, but did not present additional data of their own. (CA IOUs, No. 138 at p. 20)

DOE recognizes that shipments for certain applications are increasing very rapidly. However, DOE researched product growth trends dating back to 2006 and found that other products, like digital cameras, have seen flat shipments. Some critical applications have even had shipments decline year-over-year. There is also significant convergence in the consumer electronics industry, in which one new device may replace multiple retired devices (such as a single smart phone replacing a mobile phone, digital camera, GPS device, and PDA). DOE seeks to forecast shipments for EPSs as a whole, but given the complexity of these markets, any attempts to forecast behavior of the market will be inherently inexact. Therefore, in today's final rule, DOE decided to maintain its assumption of 0.75% growth per year from the NOPR. In its shipment forecasts, DOE projects that by 2044, shipments of EPSs will be 30 percent greater than they were in 2009.

2. Product Class Lifetime

For the NOPR, DOE calculated product class lifetime profiles using the percentage of shipments of applications within a given product class, and the lifetimes of those applications. These values were combined to estimate the percentage of units of a given vintage remaining in use in each year following the initial year in which those units were shipped and placed in service.

DOE received no comments regarding this methodology and maintained this methodology for the Final Rule. For more information on the calculation of product class lifetime profiles, see chapter 10 of the TSD.

3. Forecasted Efficiency in the Base Case and Standards Cases

A key component of the NIA is the trend in energy efficiency forecasted for the base case (without new and amended standards) and each of the standards cases. Chapter 3 of the TSD explains how DOE developed efficiency distributions (which yield shipment-weighted average efficiency) for EPS product classes for the first year of the forecast period. To project the trend in efficiency over the entire forecast period, DOE considered recent standards, voluntary programs such as ENERGY STAR, and other trends.

DOE found two programs that could influence domestic EPS efficiency in the short term: (1) The ENERGY STAR program for EPSs (called "external power adapters"), which specified that EPSs be at or above CSL 1 and (2) the European Union's (EU's) Eco-design Requirements on Energy Using Products. When the Preliminary Analysis was published, the ENERGY STAR program was very active, with more than 3,300 qualified products as of May 2010.[39] However, EPA announced that this program would end on December 31, 2010.[40] The EU program requires that EPSs sold in the EU be at or above CSL 1, effective April 2011. This program applies primarily to Class A EPSs. Recently published documents indicate that the EU is currently considering an update to its Ecodesign requirements for EPSs which would bring them to a level between levels V and VI by 2015. These documents also indicate that the EU's approach would bring the EU into harmony with DOE's proposed level VI standards by 2017. This approach, however, has not been finalized by the EU. The same documents also include a proposal for a more efficient standard—approximately 0.25% more efficient than level VI—to come into effect in 2019.[41]

Because Europe currently represents approximately one-third of the global EPS market, DOE believes that standards established by the EU will affect the U.S. market, due to the global nature of EPS design, production, and distribution. With the EU and previous ENERGY STAR programs in mind, DOE's NOPR analysis assumed that approximately half of the Class A EPS market at CSL 0 in 2009 would transition to CSL 1 by 2013 and that there would be no further improvement in the market in the absence of standards. Any EU standards that would come into effect after the beginning of the analysis period in 2015 have not been announced officially; therefore, DOE's analysis does not account for any additional improvement in EPS efficiency beyond the above discussed improvements. Aside from the comments from ARRIS Group addressed above in sections IV.A.2 and IV.C.6, DOE did not receive comments on the improvement of EPS efficiency between 2009 and the beginning of the analysis period in 2015, or other factors that may affect EPS efficiency after 2015 in the absence of federal standards. Therefore, DOE is maintaining this assumption for the Final Rule.

To estimate efficiency trends in the standards cases, DOE has used "roll-up" and/or "shift" scenarios in its standards rulemakings. Under the "roll-up" scenario, DOE assumes: (1) Product efficiencies in the base case that do not meet the standard level under consideration would "roll-up" to meet the new standard level; and (2) product efficiencies above the standard level under consideration would not be affected. Under the "shift" scenario, DOE reorients the distribution above the new minimum energy conservation standard.

In the NOPR, DOE proposed to use the "roll-up" scenario and solicited comments from stakeholders on whether such an approach is appropriate for EPSs. Delta-Q Technologies agreed with DOE's methodology (Delta-Q Technologies, No. 113 at p. 1). PTI commented that the ENERGY STAR program could provide an incentive for products to improve their efficiency (PTI, No 133 at p. 5). Because the ENERGY STAR program for EPS ended, it will not impact the EPS market going forward; therefore, DOE has maintained the "roll-up" approach for the final rule. For further details about the forecasted efficiency distributions, see chapter 9 of the TSD.

H. National Impact Analysis

The National Impact Analysis (NIA) assesses the national energy savings (NES) and the net present value (NPV) of total consumer costs and savings that would be expected to result from new and amended standards at specific efficiency levels. DOE calculates the NES and NPV based on projections of annual unit shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. DOE projected the energy savings, operating cost savings, product costs, and NPV of net consumer benefits for products sold over a 30-year period—from 2015 through 2044.

CEA commented that it is unreasonable for DOE to project shipments, energy savings, and emissions reductions over a 30-year period. Product lifecycles for many of the covered products are typically measured in months, so it can be difficult to make projections years out. (CEA, No. 106 at p. 9) Although the 30-year analysis period is longer than the average lifetime of EPSs, DOE estimates that the considered standard levels

[39] EPA, "ENERGY STAR External Power Supplies AC–DC Product List," May 24, 2010 and EPA, "ENERGY STAR External Power Supplies AC–AC Product List," May 24, 2010. Both documents last retrieved on May 28, 2010 from *http://www.energystar.gov/index.cfm?fuseaction=products_for_partners.showEPS.*

[40] EPA, "ENERGY STAR EPS EUP Sunset Decision Memo," July 19, 2010. Last retrieved on July 8, 2011 from *http://www.energystar.gov/ia/partners/prod_development/revisions/downloads/eps_eup_sunset_decision_july2010.pdf.*

[41] "Review Study on Commission Regulation (EC) No. 278/2009 External Power Supplies: Draft Final Report." March 13, 2012. Prepared for European Commission—Directorate-General for Energy. *http://www.powerint.com/sites/default/files/greenroom/docs/EPSReviewStudy_DraftFinalReport.pdf.*

analyzed will transform the market to higher energy efficiencies than in the base-case, therefore realizing energy and emission savings throughout the analysis period. Further, DOE has conducted a sensitivity analysis that projects NIA results out over nine years of shipments instead of 30 years. Results of this sensitivity analysis are available in section V.B.3 of this notice.

As in the LCC analysis, DOE evaluates the national impacts of new and amended standards by comparing base-case projections with standards-case projections. The base-case projections characterize energy use and consumer costs for each product class in the absence of new and amended energy conservation standards. DOE compares these projections with projections characterizing the market for each product class if DOE adopted new and amended standards at specific energy efficiency levels (*i.e.*, the TSLs or standards cases) for that class.

To make the analysis more accessible and transparent to all interested parties, DOE used an MS Excel spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. The TSD and other documentation that DOE provides during the rulemaking help explain the models and how to use them, and interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses average values as inputs (as opposed to probability distributions).

For today's final rule, the NIA used projections of energy prices from the *AEO 2013* Reference case. In addition, DOE analyzed scenarios that used inputs from the *AEO 2013* High Economic Growth, and Low Economic Growth cases. These cases have higher or lower energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10A to the TSD.

Table IV–13 summarizes the inputs and key assumptions DOE used in the NIA. Discussion of these inputs and changes follows the table. See chapter 10 of the TSD for further details.

TABLE IV–13—SUMMARY OF INPUTS, SOURCES AND KEY ASSUMPTIONS FOR THE NATIONAL IMPACT ANALYSIS

Inputs	NOPR description	Changes for Final rule
Base Year Shipments	Annual shipments from Market Assessment	No change.
Shipment Growth Rate	0.75 percent annually, equal to population growth.	No change.
Lifetimes	EPS lifetime is equal to the lifetime of the end-use product it powers.	No changes in methodology. Product Class lifetimes were revised based on removal of Product Class C–1 and medical products.
Base Year Efficiencies	From Market Assessment	No change.
Base-Case Forecasted Efficiencies	Efficiency distributions remain unchanged throughout the forecast period.	No change.
Standards-Case Forecasted Efficiencies	"Roll-up" scenario	No change.
Annual Energy Consumption per Unit	Annual shipment weighted-average marginal energy consumption values for each product class.	No change in the methodology. Inputs to the calculation were revised based on removal of Product Class C–1 and medical products.
Improvement Cost per Unit	From the Engineering Analysis	No change.
Markups	From Markups Analysis	No change.
Repair and Maintenance Cost per Unit	Assumed to be zero	No change.
Energy Prices	*AEO 2010* projections (to 2035) and extrapolation for 2044 and beyond.	Updated to AEO 2013.
Electricity Site-to-Source Conversion Factor	Based on *AEO 2010*	Updated to AEO 2013.
Present Year	2011	2013.
Discount Rate	3% and 7% real	No change.
Compliance Date of Standard (Start of Analysis Period).	2013	2015.

1. Product Price Trends

As noted in section IV.F.6, DOE assumed no change in EPS pricing over the 2015–2044 period in the reference case. AHAM commented that it opposes the use of "experience curves" to project price trends and agreed that DOE should not use that approach. (AHAM, No. 124 at p. 9) In contrast, PG&E and SDG&E supported DOE's consideration of falling costs in its NIA sensitivity and recommended that falling costs be incorporated into the reference case, given past declines in the costs of electronic products. (PG&E and SDG&E, No. 163 at p. 1) PSMA agreed, stating that while improvements to overall power supply efficiency do entail cost premiums, these premiums are often reduced as volumes increase and manufacturing technologies improve. (PSMA, No. 147 at p. 2)

As discussed in section IV.G.1, it is difficult to predict the consumer electronics market far in advance. To derive a price trend for EPSs, DOE did not have any historical shipments data or sufficient historical Producer Price Index (PPI) data for small electrical appliance manufacturing from the Bureau of Labor Statistics (BLS).[42] Therefore, DOE also examined a projection based on the price indexes that were projected for *AEO2012*. DOE performed an exponential fit on two deflated projected price indexes that may include the products that EPSs are components of: information equipment (Chained price index—investment in non-residential equipment and software—information equipment), and consumer durables (Chained price index—other durable goods). However, DOE believes that these indexes are too broad to accurately capture the trend for EPSs. Furthermore, most EPSs are unlike typical consumer products in that they are typically not purchased independently by consumers. Instead, they are similar to other commodities and typically bundled with end-use products.

Given the above considerations, DOE decided to use a constant price assumption as the default price factor index to project future EPSs prices in 2015. While a more conservative method, following this approach helped ensure that DOE did not understate the

[42] Series ID PCU33521–33521; *http://www.bls.gov/ppi/.*

incremental impact of standards on the consumer purchase price. Thus, DOE's product prices forecast for the LCC and PBP analysis for the final rule's analysis were held constant for each efficiency level in each product class. DOE also conducted a sensitivity analysis using alternative price trends based on AEO indexes. These price trends, and the NPV results from the associated sensitivity cases, are described in Appendix 10–B of the TSD.

2. Unit Energy Consumption and Savings

DOE uses the efficiency distributions for the base case along with the annual unit energy consumption values to estimate shipment-weighted average unit energy consumption under the base and standards cases, which are then compared against one another to yield unit energy savings values for each CSL.

To better evaluate actual energy savings when calculating unit energy consumption for a product class at a given CSL, DOE considered only those units that would actually be at that CSL and did not consider any units already at higher CSLs. That is, the shipment-weighted average unit energy consumption for a CSL ignored any shipments from higher CSLs.

In addition, when calculating unit energy consumption for a product class, DOE used marginal energy consumption, which was taken to be the consumption of a unit above the minimum energy consumption possible for that unit. Marginal unit energy consumption values were calculated by subtracting the unit energy consumption values for the highest considered CSL from the unit energy consumption values at each CSL.

As discussed in section IV.G.3, DOE assumes that energy efficiency will not improve after 2015 in the base case. Therefore, the projected UEC values in the analysis, as well as the unit energy savings values, do not vary over time. Per the roll-up scenario, the analysis assumes that manufacturers would respond to a standard by improving the efficiency of underperforming products but not those that already meet or exceed the standard.

DOE received no comments on its methodology for calculating unit energy consumption and savings in the NOPR and maintained its methodology in the final rule. For further details on the calculation of unit energy savings for the NIA, see chapter 10 of the TSD.

3. Unit Costs

DOE uses the efficiency distributions for the base case along with the unit cost values to estimate shipment-weighted average unit costs under the base and standards cases, which are then compared against one another to give incremental unit cost values for each CSL. In addition, when calculating unit costs for a product class, DOE uses that product class's marginal costs—the costs of a given unit above the minimum costs for that unit.

DOE received no comments on its methodology for calculating unit costs in the NOPR and maintained its methodology in the final rule. For further details on the calculation of unit costs for the NIA, see chapter 10 of the TSD.

4. Repair and Maintenance Cost per Unit

In the preliminary analysis and NOPR, DOE did not consider repair or maintenance costs for EPSs because the vast majority cannot be repaired and do not require any maintenance. DOE received no comments on this approach, and maintained this assumption for the Final Rule.

5. Energy Prices

While the focus of this rulemaking is on consumer products, typically found in the residential sector, DOE is aware that many products that employ EPSs are located within commercial buildings. Given this fact, the NOPR analysis relied on calculated energy cost savings from such products using commercial sector electricity rates, which are lower in value than residential sector rates. DOE used this approach so as to not overstate energy cost savings in calculating the NIA.

In order to determine the energy usage split between the residential and commercial sector, DOE first separated products into residential-use and commercial-use categories. Then, for each product class, using shipment values for 2015, average lifetimes, and base-case unit energy consumption values, DOE calculated the approximate annual energy use split between the two sectors. DOE applied the resulting ratio to the electricity pricing to obtain a sector-weighted energy price for each product class. This ratio was held constant throughout the period of analysis.

DOE received no comments on its methodology for calculating energy costs in the NOPR and maintained its approach for the final rule. For further details on the determination of energy prices for the NIA, see chapter 10 of the TSD.

6. National Energy Savings

For each year in the forecast period, DOE calculates the national energy savings for each standard level by multiplying the shipments of EPSs affected by the energy conservation standards by the per-unit annual energy savings. Cumulative energy savings are the sum of the NES for all products shipped during the analysis period, 2015–2044. Site energy savings were converted to primary energy savings using annual conversion factors derived from the *AEO 2013* version of the National Energy Modeling System (NEMS).

DOE has historically presented NES in terms of primary energy savings, as it did in the March 2012 NOPR. However, on August 17, 2012, DOE published a statement of amended policy in which it determined that all rulemakings that reach the NOPR stage after that date must present energy savings in terms of full-fuel-cycle (FFC). 77 FR 49701. Because the NOPR was published prior to August 17, 2012, DOE is maintaining its use of primary energy savings today's final rule; however, it has also decided to present FFC savings as a sensitivity analysis in order to be consistent with DOE's current standard practice. The FFC multipliers that were applied and the results of that analysis are described in appendix 10–C of the TSD.

For further details about the calculation of national energy savings, see chapter 10 of the TSD.

7. Discount Rates

The inputs for determining the NPV of the total costs and benefits experienced by consumers of EPSs are: (1) Total increased product cost, (2) total annual savings in operating costs, and (3) a discount factor. For each standards case, DOE calculated net savings each year as total savings in operating costs less total increases in product costs, relative to the base case. DOE calculated operating cost savings over the life of each product shipped from 2015 through 2044.

DOE multiplied the net savings in future years by a discount factor to determine their present value. DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (OMB) to Federal agencies on the development of regulatory analysis.[43] The 7-percent real value is an estimate of the average before-tax rate of return to private

[43] OMB Circular A–4 (Sept. 17, 2003), section E, "Identifying and Measuring Benefits and Costs. Available at: *http://www.whitehouse.gov/omb/memoranda/m03–21.html.*

capital in the U.S. economy. The 3-percent real value represents the "societal rate of time preference," which is the rate at which society discounts future consumption flows to their present value.

For further details about the calculation of net present value, see chapter 10 of the TSD.

I. Consumer Subgroup Analysis

In analyzing the potential impacts of new and amended standards, DOE evaluates the impacts on identifiable subgroups of consumers (*e.g.*, low-income households or small businesses) that may be disproportionately affected by a national standard. In the NOPR, DOE analyzed four consumer subgroups of interest—low-income consumers, small businesses, top marginal electricity price tier consumers, and consumers of specific applications within a representative unit or product class. For each subgroup, DOE considered variations on the standard inputs.

DOE defined low-income consumers as residential consumers with incomes at or below the poverty line, as defined by the U.S. Census Bureau. DOE found that these consumers face electricity prices that are 0.2 cents per kWh lower, on average, than the prices faced by consumers above the poverty line.

For small businesses, DOE analyzed the potential impacts of standards by conducting the analysis with different discount rates, as small businesses do not have the same access to capital as larger businesses. DOE estimated that for businesses purchasing EPSs, small companies have an average discount rate that is 4.5 percent higher than the industry average.

For top tier marginal electricity price consumers, DOE researched inclined marginal block rates for the residential and commercial sectors. DOE found that top tier marginal rates for general usage in the residential and commercial sectors were $0.306 and $0.221, respectively.

Lastly, for the application-specific subgroup, DOE used the inputs from each application for lifetime, markups, market efficiency distribution, and UEC to calculate LCC and PBP results. DOE's subgroup analysis for consumers of specific applications considered the LCC impacts of each application within a representative unit or product class. This approach allowed DOE to consider the LCC impacts of individual applications when choosing the proposed standard level, regardless of the application's weighting in the calculation of average impacts. The impacts of the standard on the cost of the EPS as a percentage of the application's total purchase price are not relevant to DOE's LCC analysis. The LCC considers the incremental cost between different standard levels. DOE used the cost of the EPS component, not the final price of the application, in the LCC. Therefore, a $2,000 and $20 product are assumed to have the same cost for a EPS (e.g., $5) if they are within the same CSL of the same representative unit or product class. The application-specific subgroup analyses represent an estimate of the marginal impacts of standards on consumers of each application within a representative unit or product class.

DOE received no comments on its methodology for the Consumer Subgroup Analysis in the NOPR and maintained its approach in the final rule. Chapter 11 of the TSD contains further information on the LCC analyses for all subgroups.

J. Manufacturer Impact Analysis

DOE conducted a manufacturer impact analysis (MIA) on EPSs to estimate the financial impact of new and amended energy on this industry. The MIA is both a quantitative and qualitative analysis. The quantitative part of the MIA relies on the Government Regulatory Impact Model (GRIM), an industry cash flow model customized for EPSs covered in this rulemaking. The key MIA output is industry net present value, or INPV. DOE used the GRIM to calculate cash flows using standard accounting principles and to compare the difference in INPV between the base case and various TSLs (the standards case). The difference in INPV between the base and standards cases represents the financial impact of the new and amended standards on EPS manufacturers. Different sets of assumptions (scenarios) produce different results.

DOE calculated the MIA impacts of new and amended energy conservation standards by creating a GRIM for EPS ODMs. In the GRIM, DOE grouped similarly impacted products to better analyze the effects that the new and amended standards will have on each industry. DOE presented the EPS impacts by grouping the four representative units in product class B (with output powers at 2.5, 18, 60, and 120 Watts) to characterize the results for product classes B, C, D, and E. The results for product classes X and H are presented separately.

DOE outlined its complete methodology for the MIA in the NOPR. The complete MIA is presented in chapter 12 of the final rule TSD.

1. Manufacturer Production Costs

Through the MIA, DOE attempts to model how changes in efficiency impact the manufacturer production costs (MPCs). The MPCs and the corresponding prices for which fully assembled EPSs are sold to OEMs (frequently referred to as "factory costs" in the industry) are major factors in industry value calculations. DOE's MPCs include the cost of components (including integrated circuits), other direct materials of the finalized EPS, the labor to assemble all parts, factory overhead, and all other costs borne by the ODM to fully assemble the EPS.

In the engineering analysis presented in the NOPR, DOE developed and subsequently analyzed cost-efficiency curves for four representative units in product class B and for representative units in product classes X and H. The MPCs are calculated in one of two ways, depending on product class. For the product class B representative units, DOE based its MPCs on information gathered during manufacturer interviews. In these interviews, manufacturers described the costs they would have to incur to achieve increases in energy efficiency. For product classes X and H, the engineering analysis created a complete bill of materials (BOM) derived from the disassembly of the units selected for teardown; BOM costs were used to calculate MPCs.

NRDC commented that DOE overestimated the incremental MPCs in the NOPR analysis for EPSs, particularly product class B EPSs, which caused DOE to overstate the negative financial impacts reported in the NOPR MIA. (NRDC, No. 114 at p. 21) NRDC, however, did not give any specific data supporting its view. DOE derived its MPCs from either tear-downs or direct manufacturer input. These estimates represent the most accurate and comprehensive cost data available to DOE. Accordingly, DOE continued to rely on these data in conducting its analysis and did not alter the MPCs for the final rule.

2. Product and Capital Conversion Costs

New and amended standards will cause manufacturers to incur one-time conversion costs to bring their production facilities and product designs into compliance with those standards. For the NOPR MIA, DOE classified these one-time conversion costs into two major groups: (1) Product conversion costs and (2) capital conversion costs. Product conversion costs are one-time investments in research, development, testing,

marketing, and other non-capitalized costs focused on making product designs comply with the new and amended energy conservation standards. Capital conversion costs are one-time investments in property, plant, and equipment to adapt or change existing production facilities so that new product designs can be fabricated and assembled.

In response to the NOPR, NEMA commented that the results of the manufacturer impact analysis did not accurately reflect the impact to industry, as the cost of compliance was consistently underestimated resulting in an overestimation of net savings. NEMA stated the cost to manufacturers fails to include safety and reliability testing and these testing processes are required to ensure long term efficiency gains. (NEMA, No. 134 at p. 2) DOE notes that it included the cost of safety and reliability testing as well as certification in the estimated product conversion costs for the NOPR. See chapter 12 of the TSD for a complete explanation of the conversion costs. Since NEMA did not provide any data on the costs of safety and reliability testing, DOE was unable to verify if the safety and reliability testing cost used in the NOPR were underestimated.

NRDC commented that DOE overestimated the conversion costs associated with EPS standards, which caused the MIA results to overstate the negative financial impacts on EPS manufacturers. NRDC believes the changes required by the selected standards for EPSs are simple and will only require limited capital conversion costs. (NRDC, No. 114 at p. 21) In contrast, Dell commented that DOE may have underestimated the conversion costs related to production. (Dell, Pub. Mtg. Transcript, No. 104 at p. 242) After reviewing the EPS conversion costs, DOE agrees it overstated the capital and product conversion costs because it overestimated the length of the product design cycle of the covered products. In the final rule MIA, DOE corrected its estimate of the length of the product design cycle, which reduced the EPS conversion costs by approximately 50 percent from the initial estimated conversion costs in the NOPR. See chapter 12 of this final rule TSD for further explanation.

3. Markup Scenarios

For the NOPR, DOE modeled two standards case markup scenarios in the MIA: (1) A flat markup scenario and (2) a preservation of operating profit scenario. These two scenarios represent the uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of new and amended energy conservation standards. Each scenario leads to different markup values, which when applied to the inputted MPCs, result in varying revenue and cash flow impacts.

In the flat markup scenario, DOE assumes that the cost of goods sold for each product is marked up by a flat percentage to cover SG&A expenses, R&D expenses, and profit. In the standards case for the flat markup scenario, manufacturers are able to fully pass the additional costs that are caused by standards through to their customers.

DOE also modeled the preservation of operating profit scenario in the NOPR MIA. During manufacturer interviews, ODMs and OEMs indicated that the electronics industry is extremely price sensitive throughout the distribution chain. Because of the highly competitive market, this scenario models the case in which ODMs' higher production costs for more efficient EPSs cannot be fully passed through to OEMs. In this scenario, the manufacturer markups are lowered such that manufacturers are only able to maintain the base case total operating profit in absolute dollars in the standards case, despite higher product costs and required investment. DOE implemented this scenario in the GRIM by lowering the manufacturer markups at each TSL to yield approximately the same earnings before interest and taxes in both the base case and standards cases in the year after the compliance date for the new and amended standards. This scenario generally represents the lower-bound of industry profitability following new and amended energy conservation standards because in this scenario higher production costs and the investments required to comply with new and amended energy conservation standards do not yield additional operating profit.

During the NOPR public meeting, ECOVA commented that DOE should consider a markup scenario where manufacturers can pass on the one-time conversion costs associated with new and amended energy standards. (ECOVA, Pub. Mtg. Transcript, No. 104 at p. 294) Based on the EPS market pricing conditions described during manufacturer interviews, DOE concludes that the markup scenario recommended by ECOVA is realistic and should be incorporated into the MIA. Therefore, DOE examined the INPV impacts of a return on invested capital markup scenario in the final rule MIA as a result of ECOVA's comment. The results of this markup scenario are displayed in section V.B.2.a, along with the rest of the manufacturer INPV results.

In the return on invested capital scenario, manufacturers earn the same percentage return on total capital in both the base case and standards cases in the year after the compliance date for the new and amended standards. This scenario models the situation in which manufacturers maintain a similar level of profitability from the investments required by new and amended energy conservation standards as they do from their current business operations. In the standards case under this scenario, manufacturers have higher net operating profit after taxes, but also have greater working capital and investment requirements. This scenario generally represents the upper-bound of industry profitability following new and amended energy conservation standards.

4. Impacts on Small Businesses

Cobra Electronics commented that it, and other small companies, were excluded from DOE's small business impacts analysis. Cobra stated that while it does not manufacture EPSs, it manufactures products that use EPSs and should have been included in DOE's small business impacts analysis. (Cobra Electronics, No. 130 at p. 2) DOE took into consideration only small businesses that either are directly impacted by these standards and/or manufacture EPSs domestically and found none that would be adversely affected by this rule. DOE believes that electronics manufacturers, like Cobra, that source their EPSs from other companies should not be directly examined, as the EPSs are simply one component of their products. DOE does not expect there to be any direct employment impacts on these application manufacturers that do not manufacture or design the EPSs used with their applications. Further, if these companies are not involved in the redesign or manufacturing of the EPS, they will not have significant conversion costs associated with this EPS standard. DOE acknowledges that the application price could increase due to the use of more expensive EPSs, which could negatively affect small business application manufacturers using EPSs. These price increases are the subject of the markups analysis, which is discussed in section IV.D above.

K. Emissions Analysis

In the emissions analysis, DOE estimated the reduction in power sector emissions of carbon dioxide (CO_2), nitrogen oxides (NO_X), sulfur dioxide

(SO_2), and mercury (Hg) from potential energy conservation standards for EPSs. In addition, for today's final rule, DOE developed a sensitivity analysis that estimates additional emissions impacts in production activities (extracting, processing, and transporting fuels) that provide the energy inputs to power plants. These are referred to as "upstream" emissions. Together, these emissions account for the full-fuel-cycle (FFC). In accordance with DOE's FFC Statement of Policy (76 FR 51282 (Aug. 18, 2011)), the FFC analysis includes impacts on emissions of methane (CH_4) and nitrous oxide (N_2O), both of which are recognized as greenhouse gases. The results of this FFC sensitivity analysis are described in appendix 13A of the final rule TSD.

DOE conducted the emissions analysis using emissions factors that were derived from data in EIA's *Annual Energy Outlook 2013* (*AEO 2013*), supplemented by data from other sources. DOE developed separate emissions factors for power sector emissions and upstream emissions. The method that DOE used to derive emissions factors is described in chapter 13 of the final rule TSD.

EIA prepares the *Annual Energy Outlook* using the National Energy Modeling System (NEMS). Each annual version of NEMS incorporates the projected impacts of existing air quality regulations on emissions. *AEO 2013* generally represents current legislation and environmental regulations, including recent government actions, for which implementing regulations were available as of December 31, 2012.

SO_2 emissions from affected electric generating units (EGUs) are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (DC). SO_2 emissions from 28 eastern states and DC were also limited under the Clean Air Interstate Rule (CAIR; 70 FR 25162 (May 12, 2005)), which created an allowance-based trading program that operates along with the Title IV program. CAIR was remanded to the U.S. Environmental Protection Agency (EPA) by the U.S. Court of Appeals for the District of Columbia Circuit but it remained in effect. See *North Carolina* v. *EPA*, 550 F.3d 1176 (D.C. Cir. 2008); *North Carolina* v. *EPA*, 531 F.3d 896 (D.C. Cir. 2008). On July 6, 2011 EPA issued a replacement for CAIR, the Cross-State Air Pollution Rule (CSAPR). 76 FR 48208 (August 8, 2011). On August 21, 2012, the DC Circuit issued a decision to vacate CSAPR. See *EME Homer City Generation, LP* v. *EPA*, 696 F.3d 7, 38 (D.C. Cir. 2012). The court ordered EPA to continue administering CAIR.[44] The *AEO 2013* emissions factors used for today's NOPR assumes that CAIR remains a binding regulation through 2040.

The attainment of emissions caps is typically flexible among EGUs and is enforced through the use of emissions allowances and tradable permits. Under existing EPA regulations, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by any regulated EGU. In past rulemakings, DOE recognized that there was uncertainty about the effects of efficiency standards on SO_2 emissions covered by the existing cap-and-trade system, but it concluded that negligible reductions in power sector SO_2 emissions would occur as a result of standards.

Beginning in 2015, however, SO_2 emissions will fall as a result of the Mercury and Air Toxics Standards (MATS) for power plants, which were announced by EPA on December 21, 2011. 77 FR 9304 (Feb. 16, 2012). In the final MATS rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (HAP), and also established a standard for SO_2 (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO_2 emissions will be reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. *AEO 2013* assumes that, in order to continue operating, coal plants must have either flue gas desulfurization or dry sorbent injection systems installed by 2015. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Under the MATS, NEMS shows a reduction in SO_2 emissions when electricity demand decreases (e.g., as a result of energy efficiency standards). Emissions will be far below the cap established by CAIR, so it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by any regulated EGU. Therefore, DOE believes that efficiency standards will reduce SO_2 emissions in 2015 and beyond.

CAIR established a cap on NO_X emissions in 28 eastern States and the District of Columbia. Energy conservation standards are expected to have little effect on NO_X emissions in those States covered by CAIR because excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions. However, standards would be expected to reduce NO_X emissions in the States not affected by the caps, so DOE estimated NO_X emissions reductions from the standards considered in today's final rule for these States.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would likely reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO 2013*, which incorporates the MATS.

L. Monetizing Carbon Dioxide and Other Emissions Impacts

As part of the development of the proposed rule, DOE considered the estimated monetary benefits from the reduced emissions of CO_2 and NO_X that are expected to result from each of the TSLs considered. In order to make this calculation similar to the calculation of the NPV of consumer benefits, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the forecast period for each TSL. This section summarizes the basis for the monetary values used for each of these emissions reduction estimates and presents the values considered in this rulemaking.

For today's final rule, DOE did not receive any comments on this section of the analysis and retained the same approach as in the NOPR. DOE is relying on a set of values for the social cost of carbon (SCC) that was developed by an interagency process. A summary of the basis for these values is provided below, and a more detailed description of the methodologies used is provided as an appendix to chapter 14 of the final rule TSD.

1. Social Cost of Carbon

The SCC is an estimate of the monetized damages associated with an incremental increase in carbon emissions in a given year. It is intended to include (but is not limited to) changes in net agricultural productivity, human

[44] On June 24, 2013, the Supreme Court granted certiorari in *EME Homer City. EPA* v. *EME Homer City Generation, LP*, 133 S.Ct. 2857 (2013), and has heard oral arguments on this matter on December 10, 2013. DOE notes that while the outcome of this litigation may eventually have an impact on the manner in which DOE calculates emissions impacts, accounting for those changes in the context of the present rule would be speculative given the uncertainty of the case's outcome at this time.

health, property damages from increased flood risk, and the value of ecosystem services. Estimates of the SCC are provided in dollars per metric ton of carbon dioxide. A domestic SCC value is meant to reflect the value of damages in the United States resulting from a unit change in carbon dioxide emissions, while a global SCC value is meant to reflect the value of damages worldwide.

Under section 1(b)(6) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993), agencies must, to the extent permitted by law, assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. The purpose of the SCC estimates presented here is to allow agencies to incorporate the monetized social benefits of reducing CO_2 emissions into cost-benefit analyses of regulatory actions that have small, or "marginal," impacts on cumulative global emissions. The estimates are presented with an acknowledgement of the many uncertainties involved and with a clear understanding that they should be updated over time to reflect increasing knowledge of the science and economics of climate impacts.

As part of the interagency process that developed the SCC estimates, technical experts from numerous agencies met on a regular basis to consider public comments, explore the technical literature in relevant fields, and discuss key model inputs and assumptions. The main objective of this process was to develop a range of SCC values using a defensible set of input assumptions grounded in the existing scientific and economic literatures. In this way, key uncertainties and model differences transparently and consistently inform the range of SCC estimates used in the rulemaking process.

a. Monetizing Carbon Dioxide Emissions

When attempting to assess the incremental economic impacts of carbon dioxide emissions, the analyst faces a number of serious challenges. A recent report from the National Research Council points out that any assessment will suffer from uncertainty, speculation, and lack of information about: (1) Future emissions of greenhouse gases; (2) the effects of past and future emissions on the climate system; (3) the impact of changes in climate on the physical and biological environment; and (4) the translation of these environmental impacts into economic damages. As a result, any effort to quantify and monetize the harms associated with climate change will raise serious questions of science, economics, and ethics and should be viewed as provisional.

Despite the serious limits of both quantification and monetization, SCC estimates can be useful in estimating the social benefits of reducing carbon dioxide emissions. Most Federal regulatory actions can be expected to have marginal impacts on global emissions. For such policies, the agency can estimate the benefits from reduced emissions in any future year by multiplying the change in emissions in that year by the SCC value appropriate for that year. The net present value of the benefits can then be calculated by multiplying the future benefits by an appropriate discount factor and summing across all affected years. This approach assumes that the marginal damages from increased emissions are constant for small departures from the baseline emissions path, an approximation that is reasonable for policies that have effects on emissions that are small relative to cumulative global carbon dioxide emissions. For policies that have a large (non-marginal) impact on global cumulative emissions, there is a separate question of whether the SCC is an appropriate tool for calculating the benefits of reduced emissions. This concern is not applicable to this rulemaking, however.

It is important to emphasize that the interagency process is committed to updating these estimates as the science and economic understanding of climate change and its impacts on society improves over time. In the meantime, the interagency group will continue to explore the issues raised by this analysis and consider public comments as part of the ongoing interagency process.

b. Social Cost of Carbon Values Used in Past Regulatory Analyses

Economic analyses for Federal regulations have used a wide range of values to estimate the benefits associated with reducing carbon dioxide emissions. In the final model year 2011 CAFE rule, the U.S. Department of Transportation (DOT) used both a "domestic" SCC value of $2 per metric ton of CO_2 and a "global" SCC value of $33 per metric ton of CO_2 for 2007 emission reductions (in 2007$), increasing both values at 2.4 percent per year. DOT also included a sensitivity analysis at $80 per metric ton of CO_2.[45] A 2008 regulation proposed by DOT assumed a domestic SCC value of $7 per metric ton of CO_2 (in 2006$) for 2011 emission reductions (with a range of $0–$14 for sensitivity analysis), also increasing at 2.4 percent per year.[46] A regulation for packaged terminal air conditioners and packaged terminal heat pumps finalized by DOE in October of 2008 used a domestic SCC range of $0 to $20 per metric ton CO_2 for 2007 emission reductions (in 2007$). 73 FR 58772, 58814 (Oct. 7, 2008). In addition, EPA's 2008 Advance Notice of Proposed Rulemaking on Regulating Greenhouse Gas Emissions Under the Clean Air Act identified what it described as "very preliminary" SCC estimates subject to revision. 73 FR 44354 (July 30, 2008). EPA's global mean values were $68 and $40 per metric ton CO_2 for discount rates of approximately 2 percent and 3 percent, respectively (in 2006$ for 2007 emissions).

In 2009, an interagency process was initiated to offer a preliminary assessment of how best to quantify the benefits from reducing carbon dioxide emissions. To ensure consistency in how benefits are evaluated across agencies, the Administration sought to develop a transparent and defensible method, specifically designed for the rulemaking process, to quantify avoided climate change damages from reduced CO_2 emissions. The interagency group did not undertake any original analysis. Instead, it combined SCC estimates from the existing literature to use as interim values until a more comprehensive analysis could be conducted. The outcome of the preliminary assessment by the interagency group was a set of five interim values: global SCC estimates for 2007 (in 2006$) of $55, $33, $19, $10, and $5 per metric ton of CO_2. These interim values represented the first sustained interagency effort within the U.S. government to develop an SCC for use in regulatory analysis. The results of this preliminary effort were presented in several proposed and final rules.

[45] See *Average Fuel Economy Standards Passenger Cars and Light Trucks Model Year 2011*, 74 FR 14196 (March 30, 2009) (Final Rule); Final Environmental Impact Statement Corporate Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015 at 3–90 (Oct. 2008) (Available at: *http://www.nhtsa.gov/fuel-economy*) (Last accessed December 2012).

[46] See *Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015*, 73 FR 24352 (May 2, 2008) (Proposed Rule); Draft Environmental Impact Statement Corporate Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2011–2015 at 3–58 (June 2008) (Available at: *http://www.nhtsa.gov/fuel-economy*) (Last accessed December 2012).

c. Current Approach and Key Assumptions

Since the release of the interim values, the interagency group reconvened on a regular basis to generate improved SCC estimates. Specifically, the group considered public comments and further explored the technical literature in relevant fields. The interagency group relied on three integrated assessment models commonly used to estimate the SCC: the FUND, DICE, and PAGE models. These models are frequently cited in the peer-reviewed literature and were used in the last assessment of the Intergovernmental Panel on Climate Change. Each model was given equal weight in the SCC values that were developed.

Each model takes a slightly different approach to model how changes in emissions result in changes in economic damages. A key objective of the interagency process was to enable a consistent exploration of the three models while respecting the different approaches to quantifying damages taken by the key modelers in the field. An extensive review of the literature was conducted to select three sets of input parameters for these models: climate sensitivity, socio-economic and emissions trajectories, and discount rates. A probability distribution for climate sensitivity was specified as an input into all three models. In addition, the interagency group used a range of scenarios for the socio-economic parameters and a range of values for the discount rate. All other model features were left unchanged, relying on the model developers' best estimates and judgments.

The interagency group selected four sets of SCC values for use in regulatory analyses.[47] Three sets of values are based on the average SCC from three integrated assessment models, at discount rates of 2.5 percent, 3 percent, and 5 percent. The fourth set, which represents the 95th-percentile SCC estimate across all three models at a 3-percent discount rate, is included to represent higher-than-expected impacts from climate change further out in the tails of the SCC distribution. The values grow in real terms over time. Additionally, the interagency group determined that a range of values from 7 percent to 23 percent should be used to adjust the global SCC to calculate domestic effects, although preference is given to consideration of the global benefits of reducing CO2 emissions. Table IV–14 presents the values in the 2010 interagency group report, which is reproduced in appendix 14–A of the final rule TSD.

TABLE IV–14—ANNUAL SCC VALUES FROM 2010 INTERAGENCY REPORT, 2010–2050

[In 2007 dollars per metric ton CO_2]

Year	Discount rate %			
	5	3	2.5	3
	Average	Average	Average	95th Percentile
2010	4.7	21.4	35.1	64.9
2015	5.7	23.8	38.4	72.8
2020	6.8	26.3	41.7	80.7
2025	8.2	29.6	45.9	90.4
2030	9.7	32.8	50.0	100.0
2035	11.2	36.0	54.2	109.7
2040	12.7	39.2	58.4	119.3
2045	14.2	42.1	61.7	127.8
2050	15.7	44.9	65.0	136.2

The SCC values used for today's final rule were generated using the most recent versions of the three integrated assessment models that have been published in the peer-reviewed literature.[48] Table IV–15 shows the updated sets of SCC estimates in five-year increments from 2010 to 2050. Appendix 14–B of the final rule TSD provides the full set of values. The central value that emerges is the average SCC across models at a 3-percent discount rate. However, for purposes of capturing the uncertainties involved in regulatory impact analysis, the interagency group emphasizes the importance of including all four sets of SCC values.

TABLE IV–15—ANNUAL SCC VALUES FROM 2013 INTERAGENCY UPDATE, 2010–2050

[In 2007 dollars per metric ton CO_2]

Year	Discount rate %			
	5	3	2.5	3
	Average	Average	Average	95th Percentile
2010	11	32	51	89
2015	11	37	57	109
2020	12	43	64	128
2025	14	47	69	143
2030	16	52	75	159
2035	19	56	80	175

[47] *Social Cost of Carban for Regulatory Impact Analysis Under Executive Order 12866.* Interagency Working Group on Social Cost of Carbon, United States Government, February 2010. *http://www.whitehause.gav/sites/default/files/omb/inforeg/for-agencies/Social-Cost-of-Carban-for-RIA.pdf.*

[48] *Technical Update of the Social Cast of Carbon far Regulatory Impact Analysis Under Executive Order 12866. Interagency Warking Graup an Social Cast of Carbon, United States Gavernment. May 2013; revised Navember 2013. http://www.whitehause.gav/sites/default/files/amb/assets/inforeg/technical-update-social-cost-of-carbon-for-regulatar-impact-analysis.pdf.*

TABLE IV–15—ANNUAL SCC VALUES FROM 2013 INTERAGENCY UPDATE, 2010–2050—Continued
[In 2007 dollars per metric ton CO_2]

Year	Discount rate %			
	5	3	2.5	3
	Average	Average	Average	95th Percentile
2040	21	61	86	191
2045	24	66	92	206
2050	26	71	97	220

It is important to recognize that a number of key uncertainties remain, and that current SCC estimates should be treated as provisional and revisable since they will evolve with improved scientific and economic understanding. The interagency group also recognizes that the existing models are imperfect and incomplete. The National Research Council report mentioned above points out that there is tension between the goal of producing quantified estimates of the economic damages from an incremental ton of carbon and the limits of existing efforts to model these effects. There are a number of concerns and problems that should be addressed by the research community, including research programs housed in many of the Federal agencies participating in the interagency process to estimate the SCC. The interagency group intends to periodically review and reconsider those estimates to reflect increasing knowledge of the science and economics of climate impacts, as well as improvements in modeling.

In summary, in considering the potential global benefits resulting from reduced CO_2 emissions from today's rule, DOE used the values from the 2013 interagency report, adjusted to 2012$ using the Gross Domestic Product price deflator. For each of the four cases specified, the values used for emissions in 2015 were $11.8, $39.7, $61.2, and $117 per metric ton CO_2 avoided (values expressed in 2012$). DOE derived values after 2050 using the relevant growth rate for the 2040–2050 period in the interagency update.

DOE multiplied the CO_2 emissions reduction estimated for each year by the SCC value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SCC values in each case.

2. Valuation of Other Emissions Reductions

DOE investigated the potential monetary benefit of reduced NO_X emissions from the TSLs it considered. As noted above, DOE has taken into account how new and amended energy conservation standards would reduce NOx emissions in those 22 states not affected by the CAIR. DOE estimated the monetized value of NO_X emissions reductions resulting from each of the TSLs considered for today's final rule based on estimates found in the relevant scientific literature. Available estimates suggest a very wide range of monetary values per ton of NOx from stationary sources, ranging from $468 to $4,809 per ton (in 2012$).[49] DOE calculated monetary benefits using a medium value for NO_X emissions of $2,639 per short ton (in 2012$), and real discount rates of 3 percent and 7 percent.

DOE is evaluating appropriate monetization of avoided SO_2 and Hg emissions in energy conservation standards rulemakings. It has not included this monetization in the current analysis.

The California Investor-Owned Utilities and ECOVA asked that DOE take into account the decreased cost of complying with sulfur dioxide emission regulations as a result of standards. (CA IOUs, No. 138 at p. 19; ECOVA, Pub. Mtg. Transcript, No. 104 at pp. 292–293) As discussed in section IV.L, under the MATS, SO_2 emissions are expected to be far below the cap established by CSAPR. Thus, it is unlikely that the reduction in electricity demand resulting from energy efficiency standards would have any impact on the cost of complying with the regulations.

For the final rule, DOE retained the same approach as in the NOPR for monetizing the emissions reductions from new and amended standards.

M. Utility Impact Analysis

The utility impact analysis estimates several effects on the power generation industry that would result from the adoption of new and amended energy conservation standards. In the utility impact analysis, DOE analyzes the changes in electric installed capacity and generation that result for each trial standard level. The utility impact analysis uses a variant of NEMS,[50] which is a public domain, multi-sectored, partial equilibrium model of the U.S. energy sector. DOE uses a variant of this model, referred to as NEMS–BT,[51] to account for selected utility impacts of new and amended energy conservation standards. DOE's analysis consists of a comparison between model results for the most recent *AEO* Reference Case and for cases in which energy use is decremented to reflect the impact of potential standards. The energy savings inputs associated with each TSL come from the NIA. For today's final rule, DOE did not receive any comments on this section of the analysis and retained the same approach as in the NOPR. Chapter 15 of the TSD describes the utility impact analysis in further detail.

N. Employment Impact Analysis

Employment impacts from new and amended energy conservation standards include direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the equipment subject to standards; the MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more efficient equipment. Indirect employment impacts from standards consist of the jobs created or eliminated

[49] For additional information, refer to U.S. Office of Management and Budget, Office of Information and Regulatory Affairs, 2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, Washington, DC.

[50] For more information on NEMS, refer to the U.S. Department of Energy, Energy Information Administration documentation. A useful summary is *National Energy Modeling System: An Overview 2003*, DOE/EIA–0581(2003) (March, 2003).

[51] DOE/EIA approves use of the name NEMS to describe only an official version of the model without any modification to code or data. Because this analysis entails some minor code modifications and the model is run under various policy scenarios that are variations on DOE/EIA assumptions, DOE refers to it by the name "NEMS–BT" ("BT" is DOE's Building Technologies Program, under whose aegis this work has been performed).

in the national economy, other than in the manufacturing sector being regulated, due to: (1) Reduced spending by end users on energy; (2) reduced spending on new energy supply by the utility industry; (3) increased consumer spending on the purchase of new equipment; and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Department of Labor's Bureau of Labor Statistics (BLS). BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy. There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (i.e., the utility sector) to more labor-intensive sectors (e.g., the retail and service sectors). Thus, based on the BLS data alone, DOE believes net national employment may increase because of shifts in economic activity resulting from amended standards.

For the standard levels considered in the final rule, DOE estimated indirect national employment impacts using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 3.1.1 (ImSET). ImSET is a special-purpose version of the "U.S. Benchmark National Input-Output" (I–O) model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among the 187 sectors. ImSET's national economic I–O structure is based on a 2002 U.S. benchmark table, specially aggregated to the 187 sectors most relevant to industrial, commercial, and residential building energy use. DOE notes that ImSET is not a general equilibrium forecasting model, and understands the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may over-estimate actual job impacts over the long run. For the final rule, DOE used ImSET only to estimate short-term employment impacts.

The California Energy Commission disagreed with DOE's NOPR employment impact analysis, which shows that increasing energy efficiency causes U.S. job losses. (California Energy Commission, No. 117 at p. 33) The California Energy Commission's argument was based on an assumed ratio of jobs in the consumer goods sector versus the utility sector. The California Energy Commission, however, did not provide independent data sources or references to support the assumption. As a result, DOE is maintaining its current methodology to estimate employment impacts.

DOE's employment impact analysis is designed to estimate indirect national job creation or elimination resulting from possible standards, due to reallocation of the associated expenditures for purchasing and operating EPSs. There are two cost changes to consider: reduction in energy costs from use of the product due to efficiency increase, and change in manufacturing cost to improve product energy efficiency.

Energy cost savings bring a reduction in spending on energy, which has a negative impact on employment in electric utilities and directly related sectors. Energy cost savings are assumed to be redirected according to average U.S. spending patterns; this increase in spending on all other goods and services leads to an increase in employment in all other sectors. As electric utilities are generally capital-intensive compared to the average of all sectors, the aggregate employment impact of energy cost savings is positive.

In contrast, with increased manufacturing costs, which lead to higher purchase prices, funds will be diverted from general spending, increasing spending in product manufacturing and directly related sectors. In the case of EPSs, almost all manufacturing takes place in other countries, so money flows from general spending (reducing employment across all U.S. sectors) to pay for these imported products. However, a portion of the money spent on imports returns to the U.S. when U.S. exports are sold. Because U.S. exports tend to be less labor-intensive than the average of general spending on goods and services, the aggregate impact of increased manufacturing cost is expected to be a decrease in U.S. employment.

The employment analysis in the NOPR TSD only presented impacts in the short run (2015 and 2020). In the short run, the effect from increased cost is larger than the effect from energy cost savings, which accrue over time. For this reason, DOE kept the same approach when developing the employment impact analysis for the final rule. Although DOE does not currently quantify long-run employment impacts due to modeling uncertainty, DOE anticipates that net labor market impacts will in general be negligible over time.

O. Marking Requirements

Under 42 U.S.C. 6294(a)(5), Congress granted DOE with the authority to establish labeling or marking requirements for a number of consumer products, including EPSs. DOE notes that EISA 2007 set standards for Class A EPSs and required that all Class A EPSs shall be clearly and permanently marked in accordance with the "International Efficiency Marking Protocol for External Power Supplies" (the "Marking Protocol").[52] (42 U.S.C. 6295(u)(3)(C))

The Marking Protocol, developed by the EPA in consultation with stakeholders both within and outside the United States, was originally designed in 2005 and updated in 2008 to meet the needs of those voluntary and regulatory programs in place at those times. In particular, the Marking Protocol defines efficiency mark "IV", which corresponds to the current Federal standard for Class A EPSs, and efficiency mark "V", which corresponds to ENERGY STAR version 2.0. (The ENERGY STAR program for EPSs ended on December 31, 2010.) In the 2008 version of the Marking Protocol, these marks apply only to single-voltage EPSs with nameplate output power less than 250 watts, but not to multiple-voltage or high-power EPSs. In the March 2012 NOPR, DOE indicated that it would work with the EPA and other stakeholder groups to update the Marking Protocol to accommodate any revised EPS standards it might adopt.

Brother, Panasonic, and ITI urged DOE to ensure that its marking requirements for EPSs align with the International Efficiency Marking Protocol. (Brother International, No. 111 at p. 3; ITI, No. 131 at p. 8; Panasonic, No. 120 at p. 4)

[52] U.S. EPA, "International Efficiency Marking Protocol for External Power Supplies," October 2008, available at Docket No. 62.

As noted above, EISA 2007 required all Class A EPSs to be clearly and permanently marked in accordance with the Marking Protocol—but without any reference to a particular version of that protocol.[53] In the absence of any definitive language pointing to the use of a particular version of the Marking Protocol, in DOE's view, the statute contemplated that the marking requirements would evolve over time as needed. This view is supported by the authority Congress gave to DOE in setting any necessary labeling requirements for EPSs. See 42 U.S.C. 6294(a)(5). Consistent with this authority, and the statutory foundation laid out by Congress, DOE proposed to revise the marking requirements for EPSs to accommodate the standards being adopted today. In particular, applying the already existing nomenclature pattern set out by the Marking Protocol, DOE proposed a new mark (Roman numeral VI) to denote compliance with the proposed standards. DOE has revised the Marking Protocol in collaboration with the EPA and those stakeholder groups around the world that contributed to earlier versions.

DOE received comments requesting that it not extend marking requirements to products for which such requirements do not already exist. AHAM opposed adding a marking requirement for EPSs that do not already have such requirements, noting that the usual purposes for markings—informing consumers, differentiating products in instances where there are two standards, and differentiating products that use a voluntary standard—are not served here. (AHAM, No. 124 at p. 8) AHAM and ITI commented that DOE can verify compliance with the standard by reviewing the certification and compliance statements manufacturers are already required to file with DOE, obviating the need for marking requirements, which impose additional cost and production burdens on manufacturers and result in marks that, ITI added, "consumers are likely to ignore anyway." (Id.; ITI, No. 131 at p. 8) Panasonic and AHAM commented that efficiency marking requirements for battery chargers and EPSs are unnecessary and superfluous as the covered products must comply with standards as a condition of sale in the United States. (Panasonic, No. 120 at pp. 3, 4; AHAM, No. 124 at p. 8)

DOE acknowledges that manufacturers are required to certify compliance with standards using the Compliance Certification Management System (CCMS) [54] and that, in general, markings have limited effectiveness in ensuring compliance. At the same time, DOE recognizes that manufacturers and retailers could use efficiency markings or labels to help ensure that the end-use consumer products they sell comply with all applicable standards. However, DOE has not received requests from such parties requesting additional marking requirements for such purposes. As a result, with the exception of multiple-voltage and high-power EPSs, DOE is not extending marking requirements to additional products at this time.

DOE also received comments from several manufacturers and industry associations requesting that it permit any required marking to be placed on the product's package or within accompanying documentation in lieu of placing the marking on the product itself. Specific reasons cited included: (1) Limited space on battery chargers and EPSs for additional markings, as devices have become smaller in recent years and must already have certain existing markings; (2) wide array of products of different types and sizes; (3) package labeling is less costly than marking the product itself; (4) package labeling is more visible than product markings at point of sale and at customs; (5) manufacturers would prefer to have this flexibility for product design and branding reasons; (6) such flexibility would be consistent with recent government directives on regulatory reform; and (7) product markings consume additional energy and resources. (AHAM, No. 124 at p. 9; Apple, No. 177 at p. 1; CEA, No. 137 at pp. 7–8; California Energy Commission, No. 199 at p. 12; Motorola Mobility, No. 121 at p. 16; Panasonic, No. 120 at p. 4; Philips, No. 128 at p. 6; TIA, No. 127 at p. 9)

In today's final rule, DOE is amending its marking requirements to permit any required marking to be placed on the product's package or accompanying documentation in lieu of the product itself. DOE believes that the most compelling reason for permitting more flexibility in the placement of the label is that the efficiency of the EPS can still be ascertained at any point in the distribution chain by reviewing the packaging or accompanying documentation, while allowing manufacturers to choose where to place the marking.

Several interested parties commented on the proposed marking requirements for EPSs in product class N. ITI and Panasonic commented that they see no need to require a marking on products for which standards do not apply and for which there is no provision in the Marking Protocol, i.e., non-Class A EPSs in product class N. (ITI, No. 131 at p. 9; Panasonic, No. 120 at p. 4) Panasonic further expressed concern that requiring both a Roman numeral and the letter "N" on Class A EPSs in product class N would create confusion and recommended requiring only the Roman numeral [as required at present]. (Panasonic, No. 120 at p. 4) Lastly, AHAM, NRDC, Panasonic, and Wahl Clipper all suggested ways of simplifying the marking scheme DOE proposed for EPSs in product class N. (AHAM, No. 124 at p. 8; NRDC, No. 114 at p. 17; Panasonic, No. 120 at p. 4; Wahl Clipper, Pub. Mtg. Transcript, No. 104 at p. 265)

In light of these comments, including those requesting that DOE not extend marking requirements to products for which such requirements do not already exist, DOE is not establishing a special mark for EPSs for product class N in today's final rule. For those EPSs that are already subject to standards (Class A EPSs), the Roman numeral marking requirement continues in force. For those EPSs in product class N not subject to standards (non-Class A EPSs), no efficiency marking is required. However, to ensure consistency and avoid confusion, DOE is extending the efficiency marking requirement only to those non-Class A EPSs subject to the direct operation EPS standards being adopted today, *i.e.*, multiple-voltage and high-power EPSs and the EPSs for certain battery operated motorized applications. Thus, the marking will be required for all devices that are subject to EPS standards and not required for any devices that are not subject to EPS standards.

Congress amended EPCA to exclude EPSs for certain security and life safety equipment from the no-load mode efficiency standards. Public Law 111–360 (Jan. 4, 2011) (codified at 42 U.S.C. 6295(u)(3)). The exclusion applies to AC–AC EPSs manufactured before July 1, 2017, that have (1) nameplate output

[53] "Marking.— Any class A external power supply manufactured on or after the later of July 1, 2008 or December 19, 2007, shall be clearly and permanently marked in accordance with the External Power Supply International Efficiency Marking Protocol, as referenced in the 'Energy Star Program Requirements for Single Voltage External AC–DC and AC–AC Power Supplies, version 1.1' published by the Environmental Protection Agency." 42 U.S.C. 6295(u)(3)(C). The ENERGY STAR Program Requirements v. 1.1 were announced March 1, 2006. The initial version of the International Efficiency Marking Protocol for EPSs was in effect at that time.

[54] The CCMS is an online system that permits manufacturers and third party representatives to create, submit, and track certification reports using product-specific templates. See *https://www.regulations.doe.gov/ccms.*

of 20 watts or more and (2) are certified as being designed to be connected to a security or life safety alarm or surveillance system component (as defined in the law). The provision also requires that once an EPS International Efficiency Marking Protocol is established to identify these types of EPSs, they should be permanently labeled with the appropriate mark. 42 U.S.C. 6295(u)(3)(E). Currently, no such distinguishing mark exists within the Marking Protocol. Once this mark is established, an EPS would have to be so marked to qualify for the exemption.[55]

The CEC commented that "DOE should not add EPS security marking to the international marking protocol," adding that efficiency markings are intended to identify "holistically" efficient products, covering all modes of operation. The CEC continued, "If DOE decides to adopt a marking for these products, the Energy Commission recommends using an "S" in a circle with a sunset date of July 1, 2017. This requirement should be added only to 10 CFR 430 and not to the international marking protocol." (California Energy Commission, No. 117 at p. 30) NRDC recommended that DOE adopt a marking for these products that consists of the letter "S" followed by a hyphen and the appropriate Roman numeral marking, e.g., "S–VI". (NRDC, No. 114 at p. 17)

In light of the exemption's limited scope and duration, the uncertainty about which mark to use, concerns over requiring the mark, and the irrelevance of a DOE marking requirement to determining eligibility for the exemption, DOE has decided not to adopt a special marking for the EPSs in question.

Table IV–16 summarizes the EPS marking requirements. The revised Marking Protocol (version 3.0) has been added to the docket for this rulemaking and can be downloaded from Docket EERE–2008–BT–STD–0005 on Regulations.gov.

TABLE IV–16 EPS MARKING REQUIREMENTS BY PRODUCT CLASS*

Class ID	Product class	Marking requirement
B	Direct Operation, AC–DC, Basic-Voltage	Roman numeral VI.
C	Direct Operation, AC–DC, Low-Voltage (except those with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps that charge the battery of a product that is fully or primarily motor operated).	Roman numeral VI.
C-1	Direct Operation, AC–DC, Low-Voltage with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps and charges the battery of a product that is fully or primarily motor operated.	No marking requirement.
D	Direct Operation, AC–AC, Basic-Voltage	Roman numeral VI.
E	Direct Operation, AC–AC, Low-Voltage	Roman numeral VI.
X	Direct Operation, Multiple-Voltage	Roman numeral VI.
H	Direct Operation, High-Power	Roman numeral VI.
N	Indirect Operation	Class A: Roman numeral IV or higher. Non-Class A: No marking requirement.

*An EPS not subject to standards need not be marked.

V. Analytical Results

A. Trial Standards Levels

DOE analyzed the benefits and burdens of multiple TSLs for the products that are the subject of today's rule. A description of each TSL DOE analyzed is provided below. DOE attempted to limit the number of TSLs considered for the NOPR by excluding efficiency levels that do not exhibit significantly different economic and/or engineering characteristics from the efficiency levels already selected as a TSL. While the NOPR presents only the results for those efficiency levels in TSL combinations, the TSD contains a fuller discussion and includes results for all efficiency levels that DOE examined.

Table V–1 presents the TSLs for EPSs and the corresponding efficiency levels. DOE chose to analyze product class B directly and scale the results from the engineering analysis to product classes C, D, and E. As a result, the TSLs for these three product classes correspond to the TSLs for product class B. DOE created separate TSLs for the multiple-voltage (product class X) and high-power (product class H) EPSs to determine their standards.

Table V-1 Trial Standard Levels for External Power Supplies

Product Class	Trial Standard Level		
	TSL 1	TSL 2	TSL 3
DC Output, Basic-Voltage (B)	CSL 2	CSL 3	CSL 4
DC Output, Low-Voltage (C)	Scaled Product Classes (Same CSLs as Product Class B)		
AC Output, Basic-Voltage (D)			
AC Output, Low-Voltage (E)			
Multiple Voltage (X)	CSL 1	CSL 2	CSL 3
High-Power (H)	CSL 2	CSL 3	CSL 4

[55] Note that the failure to add such a mark to the Marking Protocol or create a DOE requirement for such a mark has no bearing on the ability of such products to qualify for the exemption.

For product class B, DOE examined three TSLs corresponding to each candidate standard level of efficiency developed in the engineering analysis. TSL 1 is an intermediate level of performance above ENERGY STAR, which offers the greatest consumer NPV. TSL 2 is equivalent to the best-in-market CSL and represents an incremental rise in energy savings over TSL 1. TSL 3 is the max-tech level and corresponds to the greatest NES.

For product class X, DOE examined three TSLs above the baseline. TSL 1 is an intermediate level of performance above the baseline. TSL 2 is equivalent to the best-in-market CSL and corresponds to the maximum consumer NPV. TSL 3 is the max-tech level and corresponds to the greatest NES.

For product class H, DOE examined three TSLs above the baseline. TSL 1 corresponds to an intermediate level of efficiency. TSL 2 is the scaled best-in-market CSL and corresponds to the maximum consumer NPV. TSL 3 is the scaled max-tech level, which provides the highest NES.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

For individual consumers, measures of economic impact include the changes in LCC and the PBP associated with new and amended standards. The LCC, which is also separately specified as one of the seven factors to be considered in determining the economic justification for a new and amended standard (42 U.S.C. 6295(o)(2)(B)(i)(II)), is discussed in the following section. For consumers in the aggregate, DOE also calculates the net present value from a national perspective of the economic impacts on consumers over the forecast period used in a particular rulemaking.

a. Life-Cycle Cost and Payback Period

As in the NOPR phase, DOE calculated the average LCC savings relative to the base case market efficiency distribution for each representative unit and product class. DOE's projections indicate that a new standard would affect different EPS consumers differently, depending on the market segment to which they belong and their usage characteristics. Section IV.F discusses the inputs used for calculating the LCC and PBP. Inputs used for calculating the LCC include total installed costs, annual energy savings, electricity rates, electricity price trends, product lifetime, and discount rates.

The key outputs of the LCC analysis are average LCC savings for each product class for each considered efficiency level, relative to the base case, as well as a probability distribution of LCC reduction or increase. The LCC analysis also estimates, for each product class or representative unit, the fraction of consumers for which the LCC will either decrease (net benefit), or increase (net cost), or exhibit no change (no impact) relative to the base case forecast. No impacts occur when the product efficiencies of the base case forecast already equal or exceed the considered efficiency level. EPSs are used in applications that can have a wide range of operating hours. EPSs that are used more frequently will tend to have a larger net LCC benefit than those that are used less frequently because of the greater operating cost savings.

Another key output of the LCC analysis is the median payback period at each TSL. DOE presents the median payback period rather than the mean payback period because it is more robust in the presence of outliers in the data.[56] These outliers skew the mean payback period calculation but have little effect on the median payback period calculation. A small change in operating costs, which derive the denominator of the payback period calculation, can sometimes result in a very large payback period, which skews the mean payback period calculation. For example, consider a sample of PBPs of 2, 2, 2, and 20 years, where 20 years is an outlier. The mean PBP would return a value of 6.5 years, whereas the median PBP would return a value of 2 years. Therefore, DOE considers the median payback period, which is not skewed by occasional outliers. Table V–2 shows the results for the representative units and product classes analyzed for EPSs. Additional detail for these results, including frequency plots of the distributions of life-cycle costs and payback periods, are available in chapter 8 of the TSD.

Table V-2 LCC Savings and Payback Period for EPSs

	Weighted Average LCC Savings [2012$]			Median Payback Period [yrs]		
Rep. Unit	**TSL 1**	**TSL 2**	**TSL 3**	**TSL 1**	**TSL 2**	**TSL 3**
203W Multiple Voltage	2.33	2.38	(2.45)	0.4	4.0	11.3
345W High-Power	137.00	142.18	107.67	0.0	0.0	0.8
2.5W AC-DC, Basic V	0.21	0.17	0.17	3.0	3.7	3.7
18W AC-DC, Basic V	0.74	0.81	(0.91)	1.1	2.9	8.1
60W AC-DC, Basic V	0.57	0.90	0.60	0.9	1.3	3.1
120W AC-DC, Basic V	0.74	0.79	(4.95)	1.3	1.7	8.0

For EPS product class B (basic-voltage, AC–DC, direct operation EPSs), each representative unit has a unique value for LCC savings and median PBP. The 2.5W and 60W representative units both have positive LCC savings at all TSLs considered. The 18W and 120W representative units have positive LCC savings through TSL 2, but turn negative at TSL 3.

The non-Class A EPSs have varying LCC results at each TSL. The 203W multiple-voltage unit (product class X) has positive LCC savings through TSL 2. DOE notes that for this product class, the LCC savings remain largely the same for TSL 1 and 2 because the difference in LCC is approximately $0.01, and 95 percent of this market consists of purchased products that are already at TSL 1. Therefore, the effects are largely from the movement of the 5 percent of the market up from the baseline. The 345W high-power unit (product class H) has positive LCC savings for each TSL. This projection is largely attributable to

[56] DOE notes that it uses the median payback period to reduce the effect of outliers on the data. This method, however, does not eliminate the outliers from the data.

the installed price of the baseline unit, a linear switching device, which is more costly than higher efficiency switch-mode power devices, so as consumers move to higher efficiencies, the purchase price actually decreases, resulting in savings.

b. Consumer Subgroup Analysis

Certain consumer subgroups may be disproportionately affected by standards. DOE performed LCC subgroup analyses in this final rule for low-income consumers, small businesses, top tier marginal electricity price consumers, and consumers of specific applications. See section IV.F of this final rule for a review of the inputs to the LCC analysis. The following discussion presents the most significant results from the LCC subgroup analysis.

Low-Income Consumers

For low-income consumers, the LCC impacts and payback periods are different than for the general population. This subgroup considers only the residential sector, and uses an adjusted electricity price from the reference case scenario. DOE found that low-income consumers below the poverty line typically paid electricity prices that were 0.2 cents per kWh lower than the general population. To account for this difference, DOE adjusted electricity prices by a factor of 0.9814 to derive electricity prices for this subgroup. Table V–3 shows the LCC impacts and payback periods for low-income consumers purchasing EPSs.

The LCC savings and PBPs of low-income consumers is similar to that of the total population of consumers. In general, low-income consumers experience slightly reduced LCC savings, particularly in product classes dominated by residential applications. However, product classes with a large proportion of commercial applications experience less of an effect under the low-income consumer scenario, which is specific to the residential sector, and sometimes have greater LCC savings than the reference case results. None of the changes in LCC savings move a TSL from positive to negative LCC savings, or vice versa.

Table V-3 EPS LCC Results: Low-Income Consumer Subgroup

	Weighted Average LCC Savings [2012$]			Median Payback Period [yrs]		
Rep. Unit	**TSL 1**	**TSL 2**	**TSL 3**	**TSL 1**	**TSL 2**	**TSL 3**
203W Multiple Voltage	2.28	2.32	(2.57)	0.4	4.1	11.5
345W High-Power	134.59	139.58	104.79	0.0	0.0	0.8
2.5W AC-DC, Basic V	0.20	0.16	0.16	3.0	3.7	3.7
18W AC-DC, Basic V	0.76	0.83	(0.90)	1.1	3.0	8.9
60W AC-DC, Basic V	0.65	1.04	0.82	0.8	1.3	3.0
120W AC-DC, Basic V	0.77	0.82	(4.88)	1.2	1.6	7.8

Small Businesses

For small business consumers, the LCC impacts and payback periods are different than for the general population. This subgroup considers only the commercial sector, and uses an adjusted discount rate from the reference case scenario. DOE found that small businesses typically have a cost of capital that is 4.36 percent higher than the industry average, which was applied to the discount rate for the small business consumer subgroup.

The small business consumer subgroup LCC results are not directly comparable to the reference case LCC results because this subgroup only considers commercial applications. In the reference case scenario, the LCC results are strongly influenced by the presence of residential applications, which typically comprise the majority of application shipments. For product class B, the LCC savings become negative at TSL 2 and TSL 3 for the 2.5W representative unit under the small business scenario, and at TSL3 for the 60W unit. None of the savings for other representative units change from positive to negative, or vice versa. This observation indicates that small business consumers would experience similar LCC impacts as the general population.

Table V–4 shows the LCC impacts and payback periods for small businesses purchasing EPSs. DOE did not identify any commercial applications for non-Class A EPSs, and, consequently, did not evaluate these products as part of the small business consumer subgroup analysis.

Table V-4 EPS LCC Results: Small Business Consumer Subgroup

	Weighted Average LCC Savings [2012$]			Median Payback Period [yrs]		
Rep. Unit	**TSL 1**	**TSL 2**	**TSL 3**	**TSL 1**	**TSL 2**	**TSL 3**
2.5W AC-DC, Basic V	0.05	(0.01)	(0.05)	4.0	4.3	4.4
18W AC-DC, Basic V	0.48	0.38	(1.68)	1.0	2.4	6.1
60W AC-DC, Basic V	0.32	0.44	(0.22)	1.0	1.6	3.5
120W AC-DC, Basic V	0.52	0.52	(5.75)	1.3	1.8	8.6

Top Tier Marginal Electricity Price Consumers

For top tier marginal electricity price consumers, the LCC impacts and payback periods are different than for the general population. The analysis for this subgroup considers a weighted-average of the residential and commercial sectors and uses an adjusted electricity price from the reference case scenario. DOE used an upper tier inclined marginal block rate for the electricity price in the residential and commercial sectors, resulting in a price of $0.326 and $0.236 per kWh, respectively.

Table V–5 shows the LCC impacts and payback periods for top tier marginal electricity price consumers purchasing EPSs.

Consumers in the top tier marginal electricity price bracket experience greater LCC savings than those in the reference case scenario. This result occurs because these consumers pay more for their electricity than other consumers, and, therefore, experience greater savings when using products that are more energy efficient. This subgroup analysis increased the LCC savings of most of the representative units significantly. For the 203W multiple-voltage representative unit, the LCC savings at TSL 3 flipped from negative to positive. In product class B, for the 60W and 120W representative units, the savings also flipped from negative to positive. All other savings remained positive.

Table V-5 EPS LCC Results: Top Tier Marginal Electricity Price Consumer Subgroup

	Weighted Average LCC Savings [2012$]			Median Payback Period [yrs]		
Rep. Unit	**TSL 1**	**TSL 2**	**TSL 3**	**TSL 1**	**TSL 2**	**TSL 3**
203W Multiple Voltage	6.47	7.13	7.25	0.1	1.4	4.0
345W High-Power	331.80	351.59	340.39	0.0	0.0	0.2
2.5W AC-DC, Basic V	1.09	1.26	1.41	1.0	1.3	1.3
18W AC-DC, Basic V	2.19	3.31	3.87	0.5	1.3	3.1
60W AC-DC, Basic V	1.66	2.91	4.54	0.3	0.5	1.1
120W AC-DC, Basic V	2.29	2.68	0.62	0.5	0.6	3.5

Consumers of Specific Applications

DOE performed an LCC and PBP analysis on every application within each representative unit and product class. This subgroup analysis used the application's specific inputs for lifetime, markups, base case market efficiency distribution, and UEC. Many applications in each representative unit or product class experienced LCC impacts and payback periods that were different from the average results across the representative unit or product class. Because of the large number of applications considered in the analysis, some of which span multiple representative units or product classes, DOE did not present application-specific LCC results here. Detailed results on each application are available in chapter 11 of the TSD.

For product class B, the application-specific LCC results indicate that most applications will experience similar levels of LCC savings as the representative unit's average LCC savings. The 2.5W representative unit has positive LCC savings for each TSL, but specific applications, such as wireless headphones (among others), experience negative LCC savings. Similarly, DOE's projections for the 18W representative unit has projected positive LCC savings at TSL 1 and TSL 2, but other applications using EPSs, such as portable DVD players and camcorders, have negative savings. For the 60W representative unit, all applications follow the shipment-weighted average trends, except for at TSL 3, where two applications have negative LCC savings. For the 120W representative unit, all applications follow the shipment-weighted averages. See chapter 11 of the TSD for further detail.

c. Rebuttable Presumption Payback

As discussed in section IV.F.15, EPCA provides a rebuttable presumption that a given standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. However, DOE routinely conducts a full economic analysis that considers the full range of impacts, including those to the customer, manufacturer, Nation, and environment, as required under 42 U.S.C. 6295(o)(2)(B)(i) and 42 U.S.C. 6316(e)(1). The results of this analysis serve as the basis for DOE to evaluate definitively the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). Therefore, if the rebuttable presumption is not met, DOE may justify its standard on another basis.

For EPSs, energy savings calculations in the LCC and PBP analyses used both the relevant test procedures as well as the relevant usage profiles. Because DOE calculated payback periods using a methodology consistent with the rebuttable presumption test for EPSs in the LCC and payback period analyses, DOE did not perform a stand-alone rebuttable presumption analysis, as it was already embodied in the LCC and PBP analyses.

2. Economic Impact on Manufacturers

For the MIA in the March 2012 NOPR, DOE used changes in INPV to compare the direct financial impacts of different TSLs on manufacturers. DOE used the GRIM to compare the INPV of the base case (no new and amended energy conservation standards) to that of each TSL. The INPV is the sum of all net cash flows discounted by the industry's cost of capital (discount rate) to the base year. The difference in INPV between the base case and the standards case estimates the economic impact of implementing that standard on the entire EPS industry. For today's final rule, DOE continues to use the methodology presented in the NOPR and in section IV.J of the final rule.

a. Industry Cash Flow Analysis Results

DOE modeled three different markup scenarios using a different set of markup assumptions for each scenario after an energy conservation standard goes into effect. These assumptions produce the bounds of a range of market responses that DOE anticipates could occur in the standards case. Each markup scenario results in a unique set of cash flows and corresponding INPV at each TSL.

The first scenario DOE modeled is a flat markup scenario, or a preservation of gross margin markup scenario. The flat markup scenario assumes that in the standards case manufacturers would be able to pass the higher production costs required to manufacture more efficient products on to their customers. DOE also modeled the return on invested capital markup scenario. In this markup scenario, manufacturers maintain a similar level of profitability from the investments required by new and amended energy conservation standards as they do from their current business operations. To assess the higher (more severe) end of the range of potential impacts, DOE modeled the preservation of operating profit markup scenario. In this scenario, markups in the standards case are lowered such that manufacturers are only able to maintain their total base case operating profit in absolute dollars, despite higher product costs and investment. DOE used the main NIA shipment scenario for all MIA scenarios that were used to characterize the potential INPV impacts.

Product Classes B, C, D, and E

Table V–6 through Table V–8 present the projected results for product classes B, C, D, and E under the flat, return on invested capital, and preservation of operating profit markup scenarios. DOE examined four representative units in product class B and scaled the results to product classes C, D, and E using the most appropriate representative unit for each product class.

Table V-6 Manufacturer Impact Analysis for Product Class B, C, D, and E EPSs – Flat Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	229.1	211.2	217.5	269.1
Change in INPV	(2012$ millions)		(17.9)	(11.6)	40.0
	(%)		-7.8%	-5.1%	17.4%
Product Conversion Costs	(2012$ millions)		14.6	17.1	18.0
Capital Conversion Costs	(2012$ millions)		16.1	18.9	19.9
Total Conversion Costs	(2012$ millions)		30.7	36.1	37.9

Table V-7 Manufacturer Impact Analysis for Product Class B, C, D, and E EPSs – Return on Invested Capital Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	229.1	223.1	221.3	217.0
Change in INPV	(2012$ millions)		(6.1)	(7.8)	(12.2)
	(%)		-2.6%	-3.4%	-5.3%
Product Conversion Costs	(2012$ millions)		14.6	17.1	18.0
Capital Conversion Costs	(2012$ millions)		16.1	18.9	19.9
Total Conversion Costs	(2012$ millions)		30.7	36.1	37.9

Table V-8 Manufacturer Impact Analysis for Product Class B, C, D, and E EPSs – Preservation of Operating Profit Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	229.1	196.8	184.6	146.5
Change in INPV	(2012$ millions)		(32.3)	(44.5)	(82.7)
	(%)		-14.1%	-19.4%	-36.1%
Product Conversion Costs	(2012$ millions)		14.6	17.1	18.0
Capital Conversion Costs	(2012$ millions)		16.1	18.9	19.9
Total Conversion Costs	(2012$ millions)		30.7	36.1	37.9

At TSL 1, DOE estimates impacts on INPV to range from −$6.1 million to −$32.3 million, or a change in INPV of −2.6 percent to −14.1 percent. At this level, industry free cash flow is estimated to decrease by approximately 89.5 percent to $1.4 million, compared to the base case value of $13.6 million in the year leading up to when the amended energy conservation standards would need to be met.

At TSL 1, manufacturers of product class B, C, D, and E EPSs face a slight to moderate loss in INPV. For these product classes, the required efficiencies at TSL 1 correspond to an intermediate level above the ENERGY STAR 2.0 levels but below the best in market efficiencies. The conversion costs are a major contribution of the decrease in INPV because the vast majority of the product class B, C, D, and E EPS shipments fall below CSL 2.[57] Manufacturers will incur product and capital conversion costs of approximately $30.7 million at TSL 1. In 2015, approximately 84 percent of product class B, C, D, and E shipments are projected to fall below the proposed amended energy conservation standards. In addition, 94 percent of the products for the 2.5W representative unit are projected to fall below the proposed efficiency standard, and would likely require more substantial conversion costs because meeting the efficiency standard would require 2.5W representative units to switch from linear to switch mode technology. This change would increase the conversion costs for these 2.5W representative units, which account for approximately half of all the product class B, C, D, and E shipments.

At TSL 1, the MPC increases 45 percent for the 2.5W representative units (a representative unit for product class B and all shipments of product classes C and E), 5 percent for the 18 Watt representative units (a representative unit for product class B and all shipments of product class D), 2 percent for the 60W representative units, and 3 percent for the 120W representative units over the baseline. The conversion costs are significant enough to cause a slight negative industry impact even if manufacturers are able to maintain a similar return on their invested capital, as they do in the return on invest capital scenario. Impacts are more significant under the preservation of operating profit scenario because under this scenario manufacturers would be unable to pass on the full increase in the product cost to OEMs.

At TSL 2, DOE estimates impacts on INPV to range from −$7.8 million to −$44.5 million, or a change in INPV of −3.4 percent to −19.4 percent. At this level, industry free cash flow is estimated to decrease by approximately 105.2 percent to −$0.7 million, compared to the base case value of $13.6 million in the year before the compliance date.

TSL 2 represents the best-in-market efficiencies for product class B, C, D, and E EPSs. The increase in conversion costs and production costs at TSL 2 make the INPV impacts slightly worse than TSL 1. The product conversion costs increase by $2.5 million and the capital conversion costs increase by $2.8 million from TSL 1 because now even more products, 95 percent, fall below the efficiency requirements at TSL 2 than at TSL 1. Also, at TSL 2, the MPC increases 60 percent for the 2.5W representative units (a representative unit for product class B and all shipments of product classes C and E), 18 percent for the 18 Watt representative units (this is a representative unit for product class B and all shipments of product class D), 5 percent for the 60W representative units, and 4 percent for the 120W representative units over the baseline. However, the similar conversion costs and relatively minor additional incremental conversion costs make the industry impacts at TSL 2 similar to those at TSL 1.

At TSL 3, DOE estimates impacts on INPV to range from $40.0 million to −$82.7 million, or a change in INPV of 17.4 percent to −36.1 percent. At this level, industry free cash flow is estimated to decrease by approximately 110.5 percent to −$1.4 million, compared to the base case value of $13.6 million in the year before the compliance date.

TSL 3 represents the max-tech CSL for product class B, C, D, and E EPSs. At TSL 3, DOE modeled a wide range of industry impacts because the very large increases in per-unit production costs lead to a wide range of potential impacts depending on who captures the additional value in the distribution chain. No existing product meets the efficiency requirements at TSL 3. However, since most of the products at TSL 2 also fall below the standard level, there is only a slight difference between the conversion costs at TSL 2 and TSL 3. The different INPV impacts occur due to the large changes in incremental MPCs at the max-tech level. At TSL 3, the MPC increases 69 percent for the 2.5W representative unit (this is a representative unit for product class B and all shipments for product classes C and E), 80 percent for the 18 Watt representative units (this is a representative unit for product class B and all shipments for product class D), 24 percent for the 60W representative units, and 53 percent for the 120W representative units over the baseline. If manufacturers are able to fully pass on these costs to OEMs (the flat markup scenario), the increase in cash flow from operations is enough to overcome the conversion costs to meet the max-tech level and INPV increases moderately. However, if the manufacturers are unable to pass on these costs and only maintain the current operating profit (the preservation of operating profit markup scenario), there is a significant negative impact on INPV, because substantial increases in working capital drain operating cash flow. The conversion costs associated with switching the entire market, the large increase in incremental MPCs, and the extreme pressure from OEMs to keep product prices down make it more likely that ODMs will not be able to fully pass on these costs to OEMs and the ODMs would face a substantial loss instead of a moderate gain in INPV at TSL 3.

Product Class X

Table V–9 through Table V–11 present the projected results for product class X under the flat, return on invested capital, and preservation of operating profit markup scenarios.

[57] For a mapping of CSLs to TSLs, please see Table V–1.

Table V-9 Manufacturer Impact Analysis for Product Class X EPSs – Flat Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	44.8	44.7	39.0	46.5
Change in INPV	(2012$ millions)		(0.1)	(5.8)	1.7
	(%)		-0.3%	-13.0%	3.8%
Product Conversion Costs	(2012$ millions)		0.2	3.5	3.5
Capital Conversion Costs	(2012$ millions)		0.2	3.8	3.8
Total Conversion Costs	(2012$ millions)		0.4	7.3	7.3

Table V-10 Manufacturer Impact Analysis for Product Class X EPSs – Return on Invested Capital Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	44.8	44.7	43.5	42.9
Change in INPV	(2012$ millions)		(0.1)	(1.3)	(1.9)
	(%)		-0.2%	-3.0%	-4.2%
Product Conversion Costs	(2012$ millions)		0.2	3.5	3.5
Capital Conversion Costs	(2012$ millions)		0.2	3.8	3.8
Total Conversion Costs	(2012$ millions)		0.4	7.3	7.3

Table V-11 Manufacturer Impact Analysis for Product Class X EPSs – Preservation of Operating Profit Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	44.8	44.4	38.2	33.0
Change in INPV	(2012$ millions)		(0.4)	(6.6)	(11.8)
	(%)		-1.0%	-14.8%	-26.4%
Product Conversion Costs	(2012$ millions)		0.2	3.5	3.5
Capital Conversion Costs	(2012$ millions)		0.2	3.8	3.8
Total Conversion Costs	(2012$ millions)		0.4	7.3	7.3

At TSL 1, DOE estimates impacts on INPV to range from −$0.1 million to −$0.4 million, or a change in INPV of −0.2 percent to −1.0 percent. At this level, industry free cash flow is estimated to decrease by approximately 5.5 percent to $2.5 million, compared to the base case value of $2.7 million in the year before the compliance date.

At TSL 1, manufacturers of product class X face a very slight decline in INPV because most of the market already meets TSL 1. The total conversion costs are approximately $0.4 million. Conversion costs are low because 95 percent of the products already meet the TSL 1 efficiency requirements.

At TSL 2, DOE estimates impacts on INPV to range from −$1.3 million to −$6.6 million, or a change in INPV of −3.0 percent to −14.8 percent. At this level, industry free cash flow is estimated to decrease by approximately 109.3 percent to −$0.3 million, compared to the base case value of $2.7 million in the year leading up to when the new energy conservation standards would need to be met.

At TSL 2, manufacturers range from a slight to moderate decrease in INPV. DOE estimates that manufacturers will incur total product and capital conversion costs of $7.3 million at TSL 2. The conversion costs increase at TSL 2 because the entire market falls below the efficiency requirements at TSL 2. Also, the total impacts are driven by the incremental MPCs at TSL 2. At TSL 2, the MPC increases 16 percent over the baseline.

At TSL 3, DOE estimates impacts on INPV to range from $1.7 million to −$11.8 million, or a change in INPV of 3.8 percent to −26.4 percent. At this level, industry free cash flow is estimated to decrease by approximately 109.3 percent to −$0.3 million, compared to the base case value of $2.7

million in the year before the compliance date.

TSL 3 impacts range from a slight increase to a moderate decrease in INPV. As with TSL 2, the entire market falls below the required efficiency at TSL 3 and total industry conversion costs are also $7.3 million. However, the main difference at TSL 3 is the increase in the MPC. At TSL 3, the MPC increases 46 percent over the baseline. If the ODMs can pass on the higher price of these products to the OEMs at TSL 3, the gains from the additional revenue are outweighed by conversion costs, so manufacturers experience a slight increase in INPV. However, if ODMs cannot pass on these higher MPCs to OEMs, manufacturer experience a moderate loss in INPV. The conversion costs associated with switching the entire market, the large increase in incremental MPCs, and the extreme pressure from OEMs to keep product prices down make it more likely that ODMs will not be able to fully pass on these costs to OEMs and the ODMs would face a moderate loss instead of a slight gain in INPV at TSL 3.

Product Class H

Table V–12 through Table V–14 present the projected results for product class H under the flat, return on invested capital, and preservation of operating profit markup scenarios.

Table V-12 Manufacturer Impact Analysis for Product Class H EPSs – Flat Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	0.11	0.08	0.08	0.10
Change in INPV	(2012$ millions)		(0.03)	(0.03)	(0.01)
	(%)		-26.4%	-24.9%	-5.2%
Product Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Capital Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Total Conversion Costs	(2012$ millions)		0.02	0.02	0.02

Table V-13 Manufacturer Impact Analysis for Product Class H EPSs – Return on Invested Capital Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	0.11	0.10	0.10	0.10
Change in INPV	(2012$ millions)		(0.00)	(0.00)	(0.01)
	(%)		-3.3%	-3.4%	-4.9%
Product Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Capital Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Total Conversion Costs	(2012$ millions)		0.02	0.02	0.02

Table V-14 Manufacturer Impact Analysis for Product Class H EPSs – Preservation of Operating Profit Markup Scenario

	Units	Base Case	Trial Standard Level		
			1	2	3
INPV	(2012$ millions)	0.11	0.09	0.09	0.08
Change in INPV	(2012$ millions)		(0.01)	(0.02)	(0.03)
	(%)		-13.6%	-14.6%	-28.2%
Product Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Capital Conversion Costs	(2012$ millions)		0.01	0.01	0.01
Total Conversion Costs	(2012$ millions)		0.02	0.02	0.02

At TSL 1, DOE estimates impacts on INPV to range from less than −$10,000 to −$0.03 million, or a change in INPV of −3.3 percent to −26.4 percent. At this level, industry free cash flow is estimated to decrease by approximately

145.7 percent to less than −$10,000, compared to the base case value of $0.01 million in the year before the compliance date.

At TSL 1, manufacturers of product class H EPSs face a slight to significant loss in industry value. The base case industry value of $110,000 is low and since DOE estimates that total conversion costs at TSL 1 would be approximately $20,000, the conversion costs represent a substantial portion of total industry value. The conversion costs are high relative to the base case INPV because the entire market in 2015 is projected to fall below an efficiency standard set at TSL 1. This means that all products in product class H would have to be redesigned to meet the efficiency level at TSL 1, leading to total conversion costs that are large relative to the base case industry value. In addition, the MPC at TSL 1 declines by 21 percent compared to the baseline since the switching technology that would be required to meet this efficiency level is less costly to manufacture than improving the efficiency of baseline products that continue to use linear technology. This situation results in a lower MSP and lower revenues for manufacturers of baseline products, which exacerbates the impacts on INPV from new energy conservation standards for these products.

At TSL 2, DOE estimates impacts on INPV to range from less than −$10,000 to −$0.03 million, or a change in INPV of −3.4 percent to −24.9 percent. At this level, industry free cash flow is estimated to decrease by approximately 145.7 percent to less than −10,000, compared to the base case value of $0.01 million in the year before the compliance date.

The impacts on INPV at TSL 2 are similar to TSL 1. The conversion costs are the same since the entire market in 2015 would fall below the required efficiency at both TSL 1 and TSL 2. Also, the MPC is projected to decrease by 19 percent at TSL 2 compared to the baseline, which is similar to the 21 percent decrease at TSL 1. Overall, the similar conversion costs and lower industry revenue for the minimally compliant products make the INPV impacts at TSL 2 similar to TSL 1.

At TSL 3, DOE estimates impacts on INPV to range from −0.01 million to −$0.03 million, or a change in INPV of −4.9 percent to −28.2 percent. At this level, industry free cash flow is estimated to decrease by approximately 145.7 percent to less than −10,000, compared to the base case value of $0.01 million in the year leading up to when the new energy conservation standards would need to be met.

Impacts on INPV range from slightly to substantially negative at TSL 3. As with TSL 1 and TSL 2, the entire market falls below the required efficiency and the total industry conversion costs estimated by DOE remain at $20,000. However, the MPC increases 8 percent at TSL 3 relative to the estimated cost of the baseline unit and changes the possible impacts on INPV at TSL 3. If ODMs can maintain a similar return on invested capital in TSL 3 as in the base case, like manufacturers do in the return on invested capital scenario, the decline in INPV is only slightly negative. However, if the ODMs cannot fully pass on the higher MPCs to OEMs, as would occur in the preservation of operating profit, then the loss in INPV is much more substantial.

b. Impacts on Employment

As discussed in the March 2012 NOPR, as part of the direct employment impact analysis, DOE attempted to quantify the number of domestic workers involved in EPS manufacturing. Based on manufacturer interviews and DOE's research, DOE believes that all major EPS ODMs are foreign owned and operated. DOE did identify a few smaller niche EPS ODMs based in the U.S. and attempted to contact these companies. All of the companies DOE reached indicated their EPS manufacturing takes place abroad. During manufacturer interviews, large manufacturers also indicated the vast majority, if not all, EPS production takes place overseas. DOE also requested comment in the NOPR about the existence of any domestic EPS production and did not receive any comments. Because DOE was unable to identify any EPS ODMs with domestic manufacturing, DOE has concluded there are no EPSs currently manufactured domestically.

DOE also recognizes there are several OEMs or their domestic distributors that have employees in the U.S. that work on design, technical support, sales, training, certification, and other requirements. However, in interviews manufacturers generally did not expect any negative changes in the domestic employment of the design, technical support, or other departments of EPS OEMs located in the U.S. in response to new and amended energy conservation standards.

c. Impacts on Manufacturing Capacity

As discussed in the March 2012 NOPR, DOE does not anticipate the standards in today's final rule would adversely impact manufacturer capacity. EISA 2007 set a statutory compliance date for EPSs, and the EPS industry is characterized by rapid product development lifecycles. Therefore, DOE believes the compliance date in today's final rule provides sufficient time for manufacturers to ramp up capacity to meet the standards for EPSs.

d. Impacts on Manufacturer Subgroups

As discussed in the March 2012 NOPR, using average cost assumptions to develop an industry cash flow estimate is not adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche equipment manufacturers, and manufacturers exhibiting a cost structure substantially different from the industry average could be affected disproportionately. DOE did not identify any EPS manufacturer subgroups that would require a separate analysis in the MIA.

e. Cumulative Regulatory Burden

While any one regulation may not impose a significant burden on manufacturers, the combined effects of recent or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

During previous stages of this rulemaking, DOE identified a number of requirements, in addition to new and amended energy conservation standards for EPSs, that manufacturers of these products will face for products and equipment they manufacture within approximately three years prior to and after the anticipated compliance date of the new and amended standards. DOE discusses these and other requirements, including the energy conservation standards that take effect beginning in 2012, in its full cumulative regulatory burden analysis in chapter 12 of the TSD.

3. National Impact Analysis

a. Significance of Energy Savings

For each TSL, DOE projected energy savings for EPSs purchased in the 30-

year period that begins in the year of compliance with amended standards (2015–2044). The savings are measured over the entire lifetime of products purchased in the 30-year period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the base case. Table V–15 presents the estimated energy savings for each considered TSL, and Table V–16 presents the estimated FFC energy savings for each considered TSL. The approach used is further described in section IV.G.[58]

Table V-15 Cumulative National Energy Savings for External Power Supply Trial Standard Levels for Units Sold in 2015–2044 (quads)

Product Class	Trial Standard Level		
	1	2	3
B	0.43	0.68	1.24
B,C,D, E	0.56	0.87	1.53
X	0.06	0.07	0.14
H	0.001	0.001	0.001
Total	0.62	0.94	1.67

Table V-16 Cumulative Full-Fuel-Cycle Energy Savings for External Power Supply Trial Standard Levels for Units Sold in 2015–2044 (quads)

Product Class	Trial Standard Level		
	1	2	3
B	0.438	0.693	1.261
B,C,D, E	0.564	0.881	1.546
X	0.062	0.071	0.145
H	0.0013	0.0014	0.0015
Total*	0.627	0.944	1.69

*Total may not add up to the sum due to rounding

Circular A–4 requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using nine rather than 30-years of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of energy conservation standards and represents DOE's standard practice. We would note that the review timeframe established in EPCA generally does not overlap with the product lifetime, product manufacturing cycles or other factors specific to EPSs. In particular, DOE notes that EPS standards may be further amended and require compliance within 9 years. However, this information is presented for informational purposes only and is not indicative of any change in DOE's analytical methodology for this rulemaking. The NES results based on a 9-year analytical period are presented in Table V–17. The impacts are counted over the lifetime of products purchased in 2015–2023.

[58] Chapter 10 of the TSD presents tables that show the magnitude of the energy savings discounted at rates of 3 percent and 7 percent. Discounted energy savings represent a policy perspective in which energy savings realized farther in the future are less significant than energy savings realized in the nearer term.

Table V-17 Cumulative National Energy Savings for External Power Supply Trial Standard Levels for Units Sold in 2015–2023 (quads)

Product Class	Trial Standard Level		
	1	2	3
B	0.122	0.192	0.350
B,C,D, E	0.156	0.244	0.429
X	0.017	0.020	0.040
H	0.000	0.000	0.000
Total	0.173	0.264	0.469

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for EPSs. In accordance with OMB's guidelines on regulatory analysis,[59] DOE calculated the NPV using both a 7-percent and a 3-percent real discount rate. The 7-percent rate is an estimate of the average before-tax rate of return on private capital in the U.S. economy, and reflects the returns on real estate and small business capital as well as corporate capital. This discount rate approximates the opportunity cost of capital in the private sector (OMB analysis has found the average rate of return on capital to be near this rate). The 3-percent rate reflects the potential effects of standards on private consumption (*e.g.*, through higher prices for products and reduced purchases of energy). This rate represents the rate at which society discounts future consumption flows to their present value. It can be approximated by the real rate of return on long-term government debt (*i.e.*, yield on United States Treasury notes), which has averaged about 3 percent for the past 30-years.

Table V–18 shows the consumer NPV results for each TSL considered for EPSs. In each case, the impacts cover the lifetime of products purchased in 2015–2044.

Table V-18 Net Present Value of Consumer Benefits for External Power Supply Trial Standard Levels for Units Sold in 2015–2044 (2012$ millions)

Product Class	Discount Rate (%)	Trial Standard Level		
		1	2	3
B	3	2,358	2,830	-714
	7	1,271	1,474	-816
B,C,D, E	3	2,756	3,341	-223
	7	1,450	1,692	-662
X	3	426	441	-323
	7	233	238	-245
H	3	10	11	9
	7	5	5	4
Total	3	3,192	3,793	-537
	7	1,688	1,935	-903

The NPV results based on this 9-year analytical period are presented in Table V–19. The impacts are counted over the lifetime of products purchased in 2015–2023. As mentioned previously, this information is presented for informational purposes only and is not indicative of any change in DOE's analytical methodology or decision criteria.

[59] OMB Circular A–4, section E (Sept. 17, 2003). Available at: *http://www.whitehouse.gov/omb/circulars_a004_a-4.*

Table V-19 Net Present Value of Consumer Benefits for External Power Supplies Trial Standard Levels for Units Sold in 2015–2023 (2012$ millions)

Product Class	Discount Rate (%)	Trial Standard Level		
		1	2	3
B	3	831	979	-399
	7	612	699	-479
B,C,D, E	3	965	1,149	-247
	7	694	798	-417
X	3	152	157	-136
	7	113	115	-131
H	3	4	4	3
	7	3	3	2
Total	3	1,121	1,310	-380
	7	810	916	-546

c. Indirect Impact on Employment

From its analysis, DOE expects energy conservation standards for EPSs to reduce energy costs for consumers and the resulting net savings to be redirected to other forms of economic activity. Those shifts in spending and economic activity could affect the demand for labor. As described in section IV.N, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered in this rulemaking. DOE understands that there are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term time frames (2015–2044), where these uncertainties are reduced.

The results suggest that today's standards are likely to have negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the final rule TSD presents detailed results.

4. Impact on Utility and Performance of the Products

In establishing classes of products, and in evaluating design options and the impact of potential standard levels, DOE evaluates standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) DOE examined several classes of EPSs in its engineering analysis and used the parameters of the screening analysis to determine whether the new and amended standards would impact the utility or performance of the end-use products. Based on the results gathered for each of the EPS product classes, DOE believes that the standards adopted in today's final rule will not reduce the utility or performance of the products under consideration in this rulemaking.

5. Impact on Any Lessening of Competition

EPCA directs DOE to consider any lessening of competition that is likely to result from standards. It also directs the Attorney General of the United States (Attorney General) to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60 days of the publication of a direct final rule and simultaneously published proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(i)(V) and (B)(ii)) To assist the Attorney General in making a determination for EPS standards, DOE provided the Department of Justice (DOJ) with copies of the NOPR and the TSD for review. DOE received no adverse comments from DOJ regarding the proposal.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts or costs of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. As a measure of this reduced demand, chapter 15 in the final rule TSD presents the estimated reduction in generating capacity in 2044 for the TSLs that DOE considered in this rulemaking.

Energy savings from standards for EPSs could also produce environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases associated with electricity production. Table V–20 to Table V–23 provide DOE's estimate of cumulative CO_2, SO_2, NO_X, and Hg emission reductions projected to result from the TSLs considered in this rulemaking. DOE reports annual CO_2, SO_2, NO_X, and Hg emission reductions for each TSL in chapter 13 of the final rule TSD.

Table V-20 Cumulative Emission Reductions for Units Sold in 2015–2044 Under External Power Supply Product Class B TSLs

	Trial Standard Level		
	1	2	3
CO_2 (million metric tons)	21.6	34.2	62.3
SO_2 (thousand tons)	37.4	59.1	108
NO_X (thousand tons)	6.94	11.0	20.0
Hg (tons)	0.043	0.068	0.123

Table V-21 Cumulative Emission Reductions for Units Sold in 2015–2044 Under External Power Supply Product Class B, C, D, and E TSLs

	Trial Standard Level		
	1	2	3
CO_2 (million metric tons)	27.8	43.4	76.1
SO_2 (thousand tons)	48.4	75.5	132
NO_X (thousand tons)	8.91	13.9	24.4
Hg (tons)	0.055	0.086	0.151

Table V-22 Cumulative Emission Reductions for Units Sold in 2015–2044 Under External Power Supply Product Class X TSLs

	Trial Standard Level		
	1	2	3
CO_2 (million metric tons)	3.04	3.49	7.15
SO_2 (thousand tons)	5.30	6.09	12.5
NO_X (thousand tons)	0.975	1.12	2.29
Hg (tons)	0.006	0.007	0.014

Table V-23 Cumulative Emission Reductions for Units Sold in 2015–2044 Under External Power Supply Product Class H TSLs

	Trial Standard Level		
	1	2	3
CO_2 (million metric tons)	0.060	0.065	0.072
SO_2 (thousand tons)	0.112	0.120	0.134
NO_X (thousand tons)	0.019	0.021	0.023
Hg (tons)	0.000	0.000	0.000

As part of the analysis for this rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 and NO_X that DOE estimated for each of the TSLs considered. As discussed in section IV.M, DOE used

values for the SCC developed by an interagency process. The four sets of SCC values resulting from that process (expressed in 2012$) are represented by $11.8/metric ton (the average value from a distribution that uses a 5-percent discount rate), $39.7/metric ton (the average value from a distribution that uses a 3-percent discount rate), $61.2/metric ton (the average value from a distribution that uses a 2.5-percent discount rate), and $117/metric ton (the 95th-percentile value from a distribution that uses a 3-percent discount rate). These values correspond to the value of emission reductions in 2015; the values for later years are higher due to increasing damages as the projected magnitude of climate change increases.

Table V–24 to Table V–27 present the global value of CO_2 emission reductions at each TSL for EPSs. DOE calculated a present value of the stream of annual values using the same discount rate as was used in the studies upon which the dollar-per-ton values are based. DOE calculated domestic values as a range from 7 percent to 23 percent of the global values, and these results are presented in chapter 14 of the final rule TSD.

Table V-24 External Power Supply Product Class B: Estimates of Global Present Value of CO_2 Emission Reductions Under TSLs

TSL	SCC Case*			
	5% discount rate, average*	3% discount rate, average*	2.5% discount rate, average*	3% discount rate, 95th percentile*
	Million 2012$			
1	165	715	1,128	2,193
2	261	1,131	1,783	3,467
3	476	2,060	3,248	6,316

* For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2, and $117.0 per metric ton (2012$).

Table V-25 External Power Supply Product Classes B, C, D, and E: Estimates of Global Present Value of CO_2 Emission Reductions Under TSLs

TSL	SCC Case*			
	5% discount rate, average*	3% discount rate, average*	2.5% discount rate, average*	3% discount rate, 95th percentile*
	Million 2012$			
1	211	915	1,443	2,807
2	330	1,430	2,256	4,387
3	578	2,509	3,958	7,696

* For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2, and $117.0 per metric ton (2012$).

Table V-26 External Power Supply Product Class X: Estimates of Global Present Value of CO_2 Emission Reductions Under TSLs

TSL	SCC Case*			
	5% discount rate, average*	3% discount rate, average*	2.5% discount rate, average*	3% discount rate, 95th percentile*
	Million 2012$			
1	23.0	100	158	307
2	26.4	115	181	353
3	54.2	235	371	722

* For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2, and $117.0 per metric ton (2012$).

Table V-27 External Power Supply Product Class H: Estimates of Global Present Value of CO_2 Emission Reductions Under TSLs

TSL	SCC Case*			
	5% discount rate, average*	3% discount rate, average*	2.5% discount rate, average*	3% discount rate, 95th percentile*
	Million 2012$			
1	0.432	1.93	3.05	5.93
2	0.464	2.07	3.28	6.38
3	0.516	2.30	3.65	7.09

* For each of the four cases, the corresponding SCC value for emissions in 2015 is $11.8, $39.7, $61.2, and $117.0 per metric ton (2012$).

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other greenhouse gas (GHG) emissions to changes in the future global climate and the potential resulting damages to the world economy continues to evolve rapidly. Thus, any value placed on reducing CO_2 emissions in this rulemaking is subject to change. DOE, together with other Federal agencies, will continue to review various methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. However, consistent with DOE's legal obligations, and taking into account the uncertainty involved with this particular issue, DOE has included in this final rule the most recent values and analyses resulting from the ongoing interagency review process.

DOE also estimated a range for the cumulative monetary value of the economic benefits associated with NO_x emissions reductions anticipated to result from amended standards for EPSs. The value that DOE used is discussed in section IV.L. Table V–28 to Table V–31 present the cumulative present values for each TSL calculated using seven-percent and three-percent discount rates.

Table V-28 External Power Supply Product Class B: Estimates of Present Value of NO_X Emission Reductions Under External Power Supply TSLs

TSL	3% discount rate	7% discount rate
	Million 2012$	
1	11.2	6.6
2	17.8	10.4
3	32.4	19.0

Table V-29 External Power Supply Product Classes B, C, D, and E: Estimates of Present Value of NO_X Emission Reductions Under External Power Supply TSLs

TSL	3% discount rate	7% discount rate
	Million 2012$	
1	14.3	8.3
2	22.4	13.0
3	39.3	22.8

Table V-30 External Power Supply Product Class X: Estimates of Present Value of NO_X Emission Reductions Under External Power Supply TSLs

TSL	3% discount rate	7% discount rate
	Million 2012$	
1	1.56	0.91
2	1.80	1.04
3	3.68	2.13

Table V-31 External Power Supply Product Class H: Estimates of Present Value of NO_X Emission Reductions Under External Power Supply TSLs

TSL	3% discount rate	7% discount rate
	Million 2012$	
1	0.029	0.015
2	0.031	0.017
3	0.035	0.018

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VI)). DOE has not considered other factors in development of the standards in this final rule.

8. Summary of National Economic Impacts

The NPV of the monetized benefits associated with emissions reductions can be viewed as a complement to the NPV of the consumer savings calculated for each TSL considered in this rulemaking. Table V–32 presents the NPV values that result from adding the estimates of the potential economic benefits resulting from reduced CO_2 and NO_X emissions in each of four valuation scenarios to the NPV of consumer savings calculated for each TSL considered for EPSs, at both a three-percent and seven-percent discount rate. The CO_2 values used in the columns of each table correspond to the four sets of SCC values discussed above.

Table V-32 External Power Supplies: Net Present Value of Consumer Savings (at 7% Discount Rate) Combined with Net Present Value of Monetized Benefits from CO_2 and NO_X Emissions Reductions

Product Class	TSL	Consumer NPV at 3% Discount Rate added with (billion 2012$):			
		SCC Case $11.8/metric ton CO_2* and NO_X	SCC Case $39.7/metric ton CO_2* and NO_X	SCC Case $61.2/metric ton CO_2* and NO_X	SCC Case $117.0/metric ton CO_2* and NO_X
B,	1	2.5	3.1	3.5	4.6
	2	3.1	4.0	4.6	6.3
	3	-0.2	1.4	2.6	5.7
B, C, D, and E	1	3.0	3.7	4.2	5.6
	2	3.7	4.8	5.7	7.8
	3	0.4	2.4	3.8	7.6
X	1	0.5	0.5	0.6	0.7
	2	0.5	0.6	0.6	0.8
	3	-0.3	-0.1	0.1	0.4
H	1	0.01	0.01	0.01	0.02
	2	0.01	0.01	0.01	0.02
	3	0.01	0.01	0.01	0.02
Product Class	**TSL**	**Consumer NPV at 7% Discount Rate added with (billion 2012$):**			
		SCC Case $11.8/metric ton CO_2* and NO_X	**SCC Case $39.7/metric ton CO_2* and NO_X**	**SCC Case $61.2/metric ton CO_2* and NO_X**	**SCC Case $117.0/metric ton CO_2* and NO_X**
B	1	1.4	2.0	2.4	3.5
	2	1.7	2.6	3.3	5.0
	3	-0.3	1.3	2.5	5.5
B, C, D, and E	1	1.7	2.4	2.9	4.3
	2	2.0	3.2	4.0	6.1
	3	-0.1	1.9	3.4	7.1
X	1	0.3	0.3	0.4	0.5
	2	0.3	0.4	0.4	0.6
	3	-0.2	0.0	0.1	0.5
H	1	0.01	0.01	0.01	0.01
	2	0.01	0.01	0.01	0.01
	3	0.00	0.01	0.01	0.01

* These label values represent the global SCC in 2015, in 2012$.

Although adding the value of consumer savings to the values of emission reductions provides a valuable perspective, two issues should be considered. First, the national operating cost savings are domestic U.S. consumer monetary savings that occur as a result of market transactions, while the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and the SCC are performed with different methods that use quite different time frames for analysis. The national operating cost savings is measured for the lifetime of products shipped in 2015–2044. The SCC values, on the other hand, reflect the present value of future climate-related impacts resulting from the emission of one metric ton of CO_2 in each year. These impacts continue well beyond 2100.

C. Conclusions

When considering proposed standards, the new and amended energy conservation standard that DOE adopts for any type (or class) of covered product shall be designed to achieve the maximum improvement in energy efficiency that the Secretary of Energy determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new and amended standard must also "result in significant conservation of energy." (42 U.S.C. 6295(o)(3)(B))

For today's rulemaking, DOE considered the impacts of standards at each TSL, beginning with the max-tech level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is technologically feasible, economically justified and saves a significant amount of energy.

To aid the reader in understanding the benefits and/or burdens of each TSL, tables in this section summarize the quantitative analytical results for each TSL, based on the assumptions and methodology discussed herein. The efficiency levels contained in each TSL are described in section V.A. In addition to the quantitative results presented in the tables below, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard, and impacts on employment. Section V.B.1.b presents the estimated impacts of each TSL for the considered subgroups. DOE discusses the impacts on employment in external power supply manufacturing in section V.B.2.b and discusses the indirect employment impacts in section V.B.3.c.

1. Benefits and Burdens of Trial Standard Levels Considered for EPS Product Class B

Table V–33 and Table V–34 summarize the quantitative impacts estimated for each TSL for product class B. As explained in section IV.C.5, DOE is extending the TSLs for product class B to product classes C, D, and E because product class B was the only one directly analyzed and interested parties supported this approach because of the technical similarities among these products. The efficiency levels contained in each TSL are described in section V.A.

Table V-33 Summary of Analytical Results for EPS Product Class B: National Impacts

Category	TSL 1	TSL 2	TSL 3
National Energy Savings quads			
	0.4	0.7	1.2
NPV of Consumer Benefits 2012$ billion			
3% discount rate	2.4	2.8	-0.7
7% discount rate	1.3	1.5	-0.8
Cumulative Emissions Reduction			
CO_2 million metric tons	21.6	34.2	62.3
SO_2 thousand tons	37.4	59.1	108
NO_X thousand tons	6.94	11.0	20.0
Hg tons	0.043	0.068	0.123
Value of Emissions Reduction			
CO_2 2012$ million*	165 to 2,193	261 to 3,467	476 to 6,316
NO_X – 3% discount rate 2012$ million	11.2	17.8	32.4
NO_X – 7% discount rate 2012$ million	6.6	10.4	19.0

* Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions.

Table V-34 Summary of Analytical Results for EPS Product Class B: Manufacturer and Consumer Impacts

Category	TSL 1	TSL 2	TSL 3
Manufacturer Impacts*			
Industry NPV 2012$ million	223.1 - 196.8	221.3 - 184.6	269.1 - 146.5
Industry NPV % change	(2.6) - (14.1)	(3.4) - (19.4)	17.4 - (36.1)
Consumer Mean LCC Savings 2012$			
Representative Unit 1 (2.5W)	0.21	0.17	0.17
Representative Unit 2 (18W)	0.74	0.81	(0.91)
Representative Unit 3 (60W)	0.57	0.90	0.60
Representative Unit 4 (120W)	0.74	0.79	(4.95)
Consumer Median PBP years			
Representative Unit 1 (2.5W)	3.0	3.7	3.7
Representative Unit 2 (18W)	1.1	2.9	8.1
Representative Unit 3 (60W)	0.9	1.3	3.1
Representative Unit 4 (120W)	1.3	1.7	8.0
Representative Unit 1 (2.5W)			
Net Cost %	31.2	42.8	44.8

Category	TSL 1	TSL 2	TSL 3
Net Benefit %	61.9	55.3	55.2
No Impact %	6.8	1.9	0.0
Representative Unit 2 (18W)			
Net Cost %	16.4	35.3	70.8
Net Benefit %	54.0	53.6	29.2
No Impact %	29.6	11.1	0.0
Representative Unit 3 (60W)			
Net Cost (%)	0.0	0.0	34.7
Net Benefit (%)	81.3	98.6	65.4
No Impact (%)	18.7	1.4	0.0
Representative Unit 4 (120W)			
Net Cost (%)	0.0	2.2	100.0
Net Benefit (%)	78.5	94.9	0.0
No Impact (%)	21.5	2.9	0.0

* The manufacturer impacts presented in this table and referenced in the text below are for product classes B, C, D, and E while the consumer impacts are for product class B alone.

DOE first considered TSL 3, which represents the max-tech efficiency level. TSL 3 would save 1.2 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefits would be $-0.8 billion, using a discount rate of 7 percent, and $-0.7 billion, using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 62.3 million metric tons of CO_2, 20.0 thousand tons of NO_X, 108 thousand tons of SO_2, and 0.1 tons of Hg. The estimated monetary value of the cumulative CO_2 emissions reductions at TSL 3 ranges from $476 million to $6,316 million.

At TSL 3, the average LCC impact is a gain (consumer savings) of $0.17 for the 2.5W unit, and $0.60 for the 60W unit and a loss (LCC savings decrease) of $0.91 for the 18W unit, and $4.95 for the 120W unit. The median payback period is 3.7 years for the 2.5W unit, 8.1 years for the 18W unit, 3.1 years for the 60W unit, and 8.0 years for the 120W unit. The fraction of consumers experiencing an LCC benefit is 55.2 percent for the 2.5W unit, 29.2 percent for the 18W unit, 65.4 percent for the 60W unit, and 0.0 percent for the 120W unit. The fraction of consumers experiencing an LCC cost is 44.8 percent for the 2.5W unit, 70.8 percent for the 18W unit, 34.7 percent for the 60W unit, and 100 percent for the 120W unit.

At TSL 3, the projected change in INPV for direct operation product classes B, C, D, and E as a group ranges from a decrease of $82.7 million to an increase of $40.0 million. At TSL 3, DOE recognizes the risk of very large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high end of the range of impacts is reached, as DOE expects, TSL 3 could result in a net loss of 36.1 percent in INPV to manufacturers of EPSs in these product classes. However, as DOE has not identified any domestic manufacturers of direct operation EPSs, it does not project any immediate negative impacts on direct domestic jobs.

The Secretary concludes that at TSL 3 for EPSs in product class B, the negative NPV of consumer benefits, the economic burden on a significant fraction of consumers due to the large increases in product cost, and the capital conversion costs and profit margin impacts that could result in a very large reduction in INPV outweigh the benefits of energy savings, emission reductions, and the estimated monetary value of the CO_2 emissions reductions. Consequently, the Secretary has concluded that TSL 3 is not economically justified.

DOE then considered TSL 2. TSL 2 would save 0.7 quads of energy, an amount DOE considers significant. Under TSL 2, the NPV of consumer benefits would be $1.5 billion, using a discount rate of 7 percent, and $2.8 billion, using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 2 are 34.2 million metric tons of CO_2, 11.0 thousand tons of NO_X, 59.1 thousand tons of SO_2, and 0.1 tons of Hg. The estimated monetary value of the cumulative CO_2 emissions reductions at TSL 2 ranges from $261 million to $3,467 million.

At TSL 2, the average LCC impact is a gain (consumer savings) of $0.17 for the 2.5W unit, $0.81 for the 18W unit, $0.90 for the 60W unit, and $0.79 for the 120W unit. The median payback period is 3.7 years for the 2.5W unit, 2.9 years for the 18W unit, 1.3 years for the 60W unit, and 1.7 years for the 120W unit. The fraction of consumers experiencing an LCC benefit is 55.3 percent for the 2.5W unit, 53.6 percent for the 18W unit, 98.6 percent for the 60W unit, and 94.9 percent for the 120W unit. The fraction of consumers experiencing an LCC cost is 42.8 percent for the 2.5W unit, 35.3 percent for the 18W unit, 0.0 percent for the 60W unit, and 2.2 percent for the 120W unit.

At TSL 2, the projected change in INPV for product classes B, C, D, and E as a group ranges from a decrease of $44.5 million to a decrease of $7.8 million. DOE recognizes the risk of large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high end of the range of impacts is reached, as DOE expects, TSL 2 could result in a net loss of 19.4 percent in INPV to manufacturers of EPSs in these product classes.

The Secretary concludes that at TSL 2 for EPSs in product class B, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the CO_2 emissions reductions outweigh the economic burden on a significant fraction of consumers due to the increases in product cost and the capital conversion costs and profit margin impacts that could result in a reduction in INPV to manufacturers.

After considering the analysis, public comments on the NOPR, and the benefits and burdens of TSL 2, the Secretary concludes that this TSL will offer the maximum improvement in efficiency that is technologically feasible and economically justified and will result in the significant conservation of energy. Therefore, DOE today is adopting standards at TSL 2 for EPSs in product class B and, by extension, for EPSs in product classes C, D, and E. The new and amended energy conservation standards for these EPSs, expressed as equations for minimum average active-mode efficiency and maximum no-load input power, are shown in Table V–35.

Table V-35 Standards for EPSs in Product Classes B, C, D, and E

Direct Operation External Power Supplies – Product Class B: AC-DC, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 * P_{out} + 0.16$	≤ 0.100
1 W < $P_{out} \leq 49$ W	$\geq 0.071 * \ln(P_{out}) - 0.0014 * P_{out} + 0.67$	≤ 0.100
49 W < $P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
Direct Operation External Power Supplies – Product Class C: AC-DC, Low-Voltage*		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 * P_{out} + 0.087$	≤ 0.100
1 W < $P_{out} \leq 49$ W	$\geq 0.0834 * \ln(P_{out}) - 0.0014 * P_{out} + 0.609$	≤ 0.100
49 W < $P_{out} \leq 250$ W	≥ 0.870	≤ 0.210
Direct Operation External Power Supplies – Product Class D: AC-AC, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode**
$P_{out} \leq 1$ W	$\geq 0.5 * P_{out} + 0.16$	≤ 0.210
1 W < $P_{out} \leq 49$ W	$\geq 0.071 * \ln(P_{out}) - 0.0014 * P_{out} + 0.67$	≤ 0.210
49 W < $P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
Direct Operation External Power Supplies – Product Class E: AC-AC, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode**
$P_{out} \leq 1$ W	$\geq 0.517 * P_{out} + 0.087$	≤ 0.210
1 W < $P_{out} \leq 49$ W	$\geq 0.0834 * \ln(P_{out}) - 0.0014 * P_{out} + 0.609$	≤ 0.210
49 W < $P_{out} \leq 250$ W	≥ 0.870	≤ 0.210

* Excludes any EPS with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps that charges the battery of a product that is fully or primarily motor operated.

2. Benefits and Burdens of Trial Standard Levels Considered for EPS Product Class X

Table V–36 and Table V–37 present a summary of the quantitative impacts estimated for each TSL for multiple-voltage EPSs. The efficiency levels contained in each TSL are described in section V.A.

Table V-36 Summary of Analytical Results for EPS Product Class X: National Impacts

Category	TSL 1	TSL 2	TSL 3
National Energy Savings quads			
	0.06	0.07	0.14
NPV of Consumer Benefits 2012$ billion			
3% discount rate	0.43	0.44	-0.32
7% discount rate	0.23	0.24	-0.25
Cumulative Emissions Reduction			
CO_2 million metric tons	3.04	3.49	7.15
SO_2 thousand tons	5.30	6.09	12.5
NO_X thousand tons	0.975	1.12	2.29
Hg tons	0.006	0.007	0.014
Value of Emissions Reduction			
CO_2 2012$ million*	23.0 to 307	26.4 to 353	54.2 to 722
NO_X – 3% discount rate 2012$ million	1.56	1.8	3.68
NO_X – 7% discount rate 2012$ million	0.91	1.04	2.13

* Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions.

Table V-37 Summary of Analytical Results for EPS Product Class X: Manufacturer and Consumer Impacts

Category	TSL 1	TSL 2	TSL 3
Manufacturer Impacts			
Industry NPV 2012$ million	44.7 - 44.4	43.5 - 38.2	46.5 - 33.0
Industry NPV % change	(0.2) - (1.0)	(3.0) - (14.8)	3.8 - (26.4)
Consumer Mean LCC Savings 2012$			
Representative Unit 1	2.33	2.88	(2.45)
Consumer Median PBP years			
Representative Unit 1	0.4	4.0	11.3
Representative Unit 1			
Net Cost %	0.0	25.5	95.0
Net Benefit %	5.0	74.6	5.0
No Impact %	95.0	0.0	0.0

DOE first considered TSL 3, which represents the max-tech efficiency level. TSL 3 would save 0.14 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefits would be $-0.25 billion, using a discount rate of 7 percent, and $-0.32 billion, using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 7.2 million metric tons of CO_2, 2.3 thousand tons of NO_X, 12.5 thousand tons of SO_2, and 0.01 tons of Hg. The estimated monetary value of the

cumulative CO_2 emissions reductions at TSL 3 ranges from $54.2 million to $722 million.

At TSL 3, the average LCC impact is a cost (LCC savings decrease) of $2.45. The median payback period is 11.3 years. The fraction of consumers experiencing an LCC benefit is 5.0 percent while the fraction of consumers experiencing an LCC cost is 95.0 percent.

At TSL 3, the projected change in INPV ranges from a decrease of $11.8 million to an increase of $1.7 million. At TSL 3, DOE recognizes the risk of very large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high range of impacts is reached, as DOE expects, TSL 3 could result in a net loss of 26.4 percent in INPV to manufacturers of multiple-voltage EPSs. However, as DOE has not identified any domestic manufacturers of multiple-voltage EPSs, it does not project any immediate negative impacts on direct domestic jobs.

The Secretary concludes that at TSL 3 for multiple-voltage EPSs, the negative NPV of consumer benefits, the economic burden on a significant fraction of consumers due to the large increases in product cost, and the capital conversion costs and profit margin impacts that could result in a very large reduction in INPV outweigh the benefits of energy savings, emission reductions, and the estimated monetary value of the CO_2 emissions reductions. Consequently, the Secretary has concluded that TSL 3 is not economically justified.

DOE then considered TSL 2. TSL 2 would save 0.07 quads of energy, an amount DOE considers significant. Under TSL 2, the NPV of consumer benefits would be $0.24 billion, using a discount rate of 7 percent, and $0.44 billion, using a discount rate of 3 percent.

At TSL 2, the average LCC impact is a gain (consumer savings) of $2.88. The median payback period is 4.0 years. The fraction of consumers experiencing an LCC benefit is 74.6 percent while the fraction of consumers experiencing an LCC cost is 25.5 percent.

The cumulative emissions reductions at TSL 2 are 3.5 million metric tons of CO_2, 1.1 thousand tons of NO_X, 6.1 thousand tons of SO_2, and less than 0.01 tons of Hg. The estimated monetary value of the cumulative CO_2 emissions reductions at TSL 2 ranges from $26.4 million to $353 million.

At TSL 2, the projected change in INPV ranges from a decrease of $6.6 million to a decrease of $1.3 million. At TSL 2, DOE recognizes the risk of large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high end of the range of impacts is reached, as DOE expects, TSL 2 could result in a net loss of 14.8 percent in INPV to manufacturers of multiple-voltage EPSs.

The Secretary concludes that at TSL 2 for multiple-voltage EPSs, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the CO_2 emissions reductions outweigh the economic burden on a significant fraction of consumers due to the increases in product cost and the capital conversion costs and profit margin impacts that could result in a reduction in INPV for manufacturers.

After considering the analysis, public comments on the NOPR, and the benefits and burdens of TSL 2, the Secretary concludes that this TSL will offer the maximum improvement in efficiency that is technologically feasible and economically justified and will result in the significant conservation of energy. Therefore, DOE today is adopting standards at TSL 2 for multiple-voltage EPSs. The new energy conservation standards for these EPSs, expressed as equations for minimum average active-mode efficiency and maximum no-load input power, are shown in Table V–38.

Table V-38 Standards for External Power Supplies in Product Class X

Direct Operation External Power Supplies – Product Class X: Multiple Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.497 * P_{out} + 0.067$	≤ 0.300
1 W < $P_{out} \leq 49$ W	$\geq 0.075 * \ln(P_{out}) + 0.561$	≤ 0.300
$P_{out} > 49$ W	≥ 0.860	≤ 0.300

3. Benefits and Burdens of Trial Standard Levels Considered for EPS Product Class H

Table V–39 and Table V–40 present a summary of the quantitative impacts estimated for each TSL for high-power EPSs. The efficiency levels contained in each TSL are described in section V.A.

Table V-39 Summary of Analytical Results for EPS Product Class H: National Impacts

Category	TSL 1	TSL 2	TSL 3
National Energy Savings quads			
	0.0012	0.0013	0.0015
NPV of Consumer Benefits 2012$ billion			
3% discount rate	0.010	0.011	0.009
7% discount rate	0.005	0.005	0.004
Cumulative Emissions Reduction			
CO_2 million metric tons	0.060	0.065	0.072
SO_2 thousand tons	0.112	0.120	0.134
NO_X thousand tons	0.019	0.021	0.023
Hg tons	0.000	0.000	0.000
Value of Emissions Reduction			
CO_2 2012$ million*	0.432 to 5.93	0.464 to 6.38	0.516 to 7.09
NO_X – 3% discount rate 2012$ million	0.029	0.031	0.035
NO_X – 7% discount rate 2012$ million	0.015	0.017	0.018

* Range of the economic value of CO_2 reductions is based on estimates of the global benefit of reduced CO_2 emissions.

Table V-40 Summary of Analytical Results for EPS Product Class H: Manufacturer and Consumer Impacts

Category	TSL 1	TSL 2	TSL 3
Manufacturer Impacts			
Industry NPV 2012$ million	0.10 - 0.08	0.10 - 0.08	0.10 - 0.08
Industry NPV % change	(3.3) - (26.4)	(3.4) - (24.9)	(4.9) - (28.2)
Consumer Mean LCC Savings 2012$			
Representative Unit 1	137.00	142.18	107.67
Consumer Median PBP years			
Representative Unit 1	0.0	0.0	0.8
Representative Unit 1			
Net Cost %	0.0	0.0	9.7
Net Benefit %	100.0	100.0	90.3
No Impact %	0.0	0.0	0.0

DOE first considered TSL 3, which represents the max-tech efficiency level. TSL 3 would save 0.0015 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefits would be $0.004 billion, using a discount rate of 7 percent, and $0.009 billion, using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 0.07 million metric tons of CO_2, 0.02 thousand tons of NO_X, 0.1 thousand tons of SO_2, and less than 0.001 tons of Hg. The estimated monetary value of the cumulative CO_2 emissions reductions at TSL 3 ranges from less than $0.52 to $7.09 million.

At TSL 3, the average LCC impact is a gain (consumer savings) of $107.67. The median payback period is 0.8 years. The fraction of consumers experiencing an LCC benefit is 90.3 percent while the fraction of consumers experiencing an LCC cost is 9.7 percent.

At TSL 3, the projected change in INPV ranges from a decrease of $0.03 million to a decrease of $0.01 million. At TSL 3, DOE recognizes the risk of very large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high end of the range of impacts is reached, as DOE expects, TSL 3 could

result in a net loss of 28.2 percent in INPV to manufacturers of high-power EPSs. However, as DOE has not identified any domestic manufacturers of high-power EPSs, it does not project any immediate negative impacts on direct domestic jobs.

The Secretary concludes that at TSL 3 for high-power EPSs, the additional considerations of the potential negative impacts of a standard at this max-tech TSL outweigh the benefits of energy savings, emission reductions, and the estimated monetary value of the CO_2 emissions reductions. DOE notes that it scaled results from product class B to estimate the cost and efficiency of this max-tech CSL. Consequently, DOE is unaware of any product that can achieve this efficiency level in either product class B or H. Thus, although DOE's analysis indicates that the max-tech efficiency level is achievable, there is a risk that unforeseen obstacles remain to creating an EPS at this efficiency level.

Additionally, setting a standard at TSL 3 would create a discontinuity in the active mode efficiency standards for EPSs. For product class B devices, the active mode efficiency standard is constant for nameplate output power ratings greater than 49 watts up to 250 watts. At 250 watts, where product class H begins, the active mode efficiency standard would increase by 4 percentage points if DOE set standards for this product class at the max-tech CSL. This discontinuity in efficiency between the two product classes would be the result of the standards for product class B being equivalent to the best-in-market CSL equation while the standards for product class H would be equivalent to the max-tech CSL equation for high-power EPSs.

In contrast, by applying the same level of stringency, scaled for the representative unit voltage, to all EPSs with output power greater than 250 watts, the achievable efficiency in EPS designs that have an output power above 49 watts remains nearly constant. This result occurs because the switching and conduction losses associated with the EPS remain proportionally the same with the increase in output power, which creates a relatively flat achievable efficiency above 49 watts. If DOE were to adopt a level that created a discontinuity in the efficiency levels, it would ignore this trend and set a higher efficiency standard between two product classes despite numerous technical similarities. Consequently, the Secretary has concluded that TSL 3 is not justified.

DOE then considered TSL 2. TSL 2 would save 0.0013 quads of energy an amount DOE considers significant. Under TSL 2, the NPV of consumer benefits would be $0.005 billion, using a discount rate of 7 percent, and $0.0011 billion, using a discount rate of 3 percent.

At TSL 2, the average LCC impact is a gain (consumer savings) of $142.18. The median payback period is 0.0 years. The fraction of consumers experiencing an LCC benefit is 100.0 percent while the fraction of consumers experiencing an LCC cost is 0.0 percent.

The cumulative emissions reductions at TSL 2 are 0.07 million metric tons of CO_2, 0.02 thousand tons of NO_X, 0.12 thousand tons of SO_2, and less than 0.001 tons of Hg. The estimated monetary value of the cumulative CO_2 emissions reductions at TSL 2 ranges from less than $0.46 to $6.38 million.

At TSL 2, the projected change in INPV ranges from a decrease of $0.03 million to a decrease of less than $10,000. At TSL 2, DOE recognizes the risk of large negative impacts if manufacturers' expectations concerning reduced profit margins are realized. If the high end of the range of impacts is reached, as DOE expects, TSL 2 could result in a net loss of 24.9 percent in INPV to manufacturers of high-power EPSs.

The Secretary concludes that at TSL 2 for high-power EPSs, the benefits of energy savings, positive NPV of consumer benefits, positive LCC savings for all consumers, emission reductions, and the estimated monetary value of the CO_2 emissions reductions outweigh the economic burden of the capital conversion costs and profit margin impacts that could result in a reduction in INPV for manufacturers.

After considering the analysis, public comments on the NOPR, and the benefits and burdens of TSL 2, the Secretary concludes that this TSL will offer the maximum improvement in efficiency that is technologically feasible and economically justified and will result in the significant conservation of energy. Therefore, DOE today is adopting standards at TSL 2 for EPSs in product class H. The new energy conservation standards for these EPSs, expressed as a minimum average active-mode efficiency value and a maximum no-load input power value, are shown in Table V–41.

Table V-41 Standards for High-Power External Power Supplies

Direct Operation External Power Supplies – Product Class H: High-Power		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} > 250$ W	≥ 0.875	≤ 0.500

4. Summary of Benefits and Costs (Annualized) of the Proposed Standards

The benefits and costs of today's standards, for products sold in 2015–2044, can also be expressed in terms of annualized values. The annualized monetary values are the sum of (1) the annualized national economic value of the benefits from operating the product (consisting primarily of operating cost savings from using less energy, minus increases in equipment purchase and installation costs, which is another way of representing consumer NPV), plus (2) the annualized monetary value of the benefits of emission reductions, including CO_2 emission reductions.[60]

Although adding the value of consumer savings to the value of

[60] DOE used a two-step calculation process to convert the time-series of costs and benefits into annualized values. First, DOE calculated a present value in 2013, the year used for discounting the NPV of total consumer costs and savings, for the time-series of costs and benefits using discount rates of three and seven percent for all costs and benefits except for the value of CO_2 reductions. For the latter, DOE used a range of discount rates, as shown in Table I.3. From the present value, DOE then calculated the fixed annual payment over a 30-year period (2015 through 2044) that yields the same present value. The fixed annual payment is the annualized value. Although DOE calculated annualized values, this does not imply that the time-series of cost and benefits from which the annualized values were determined is a steady stream of payments.

emission reductions provides a valuable perspective, two issues should be considered. First, the national operating cost savings are domestic U.S. consumer monetary savings that occur as a result of market transactions, while the value of CO_2 reductions is based on a global value. Second, the assessments of operating cost savings and CO_2 savings are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of EPSs shipped in 2015–2044. The SCC values, on the other hand, reflect the present value of all future climate-related impacts resulting from the emission of one metric ton of carbon dioxide in each year. These impacts continue well beyond 2100.

Estimates of annualized benefits and costs of today's standards are shown in Table V–42. The results under the primary estimate are as follows. Using a 7-percent discount rate for benefits and costs other than CO_2 reduction, for which DOE used a 3-percent discount rate along with the average SCC series that uses a 3-percent discount rate, the cost of the standards in today's rule is $147 million per year in increased equipment costs, while the benefits are $293 million per year in reduced equipment operating costs, $77 million in CO_2 reductions, and $1.1 million in reduced NO_X emissions. In this case, the net benefit amounts to $223 million per year. Using a 3-percent discount rate for all benefits and costs and the average SCC series, the cost of the standards in today's rule is $162 million per year in increased equipment costs, while the benefits are $350 million per year in reduced operating costs, $77 million in CO_2 reductions, and $1.2 million in reduced NO_X emissions. In this case, the net benefit amounts to $266 million per year.

Table V-42 Annualized Benefits and Costs of New and Amended Standards for EPSs, in Million 2012$

	Discount Rate	Primary Estimate*	Low Net Benefits Estimate*	High Net Benefits Estimate*
		million 2012$/year		
Benefits				
Consumer Operating Cost Savings	7%	293	292	298
	3%	350	347	356
CO_2 Reduction ($11.8/t case)**	5%	22	22	22
CO_2 Reduction ($39.7/t case)**	3%	77	77	77
CO_2 Reduction ($61.2/t case)**	2.5%	114	114	114
CO_2 Reduction ($117.0/t case)**	3%	235	235	235
NO_X Reduction at $2,639/ton**	7%	1.06	1.06	1.06
	3%	1.20	1.20	1.20
Total Benefits†	7% plus CO_2 range	316 to 529	315 to 528	321 to 534
	7%	371	369	375
	3% plus CO_2 range	373 to 586	370 to 583	379 to 592
	3%	428	425	434
Costs				
Consumer Incremental Product Costs	7%	147	147	94
	3%	162	162	96
Net Benefits				
Total†	7% plus CO_2 range	169 to 382	168 to 381	227 to 440
	7%	223	222	281
	3% plus CO_2 range	211 to 424	209 to 422	284 to 497
	3%	266	263	338

* This table presents the annualized costs and benefits associated with EPSs shipped in 2015 - 2044. These results include benefits to consumers which accrue after 2044 from EPSs purchased from 2015 - 2044. Costs incurred by manufacturers, some of which may be incurred prior to 2015 in preparation for the rule, are not directly included, but are indirectly included as part of incremental equipment costs. The Primary, Low Benefits, and High Benefits Estimates utilize projections of energy prices from the AEO 2013 Reference case, Low Estimate, and High Estimate, respectively. In addition, incremental product costs reflect a constant rate for projected product price trends in the Primary Estimate, a constant rate for projected product price trends in the Low Benefits Estimate, and a declining rate for projected product price trends in the High Benefits Estimate. The methods used to derive projected price trends are explained in section IV.F.1.

** The interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the three integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth set, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, is included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The values in parentheses represent the SCC in 2015. The SCC time series incorporate an escalation factor. The value for NO_X is the average of the low and high values used in DOE's analysis.

† Total Benefits for both the 3-percent and 7-percent cases are derived using the series corresponding to average SCC with 3-percent discount rate. In the rows labeled "7% plus CO_2 range" and "3% plus CO_2 range," the operating cost and NO_X benefits are calculated using the labeled discount rate, and those values are added to the full range of CO_2 values.

5. Stakeholder Comments on Alternatives to Standards

Cobra Electronics commented that the ENERGY STAR program is an effective means for encouraging the development of more efficient technologies. Furthermore, the use of a voluntary program would allow DOE to comply with Executive Order 13563, which directed federal agencies to "identify and assess available alternatives to direct regulation." (Cobra Electronics, No. 130 at p. 8) Executive Order 13563 also states that regulations should be adopted "only upon a reasoned determination that its benefits justify its costs." Because the selected standard levels are technologically feasible and economically justified, DOE has fulfilled its statutory obligations as well as the directives in Executive Order 13563. In addition, DOE considered the impacts of a voluntary program as part of the Regulatory Impact Analysis and found that such a program would save less energy than standards (see chapter 17 of the TSD).

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Section 1(b)(1) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993), requires each agency to identify the problem that it intends to address, including, where applicable, the failures of private markets or public institutions that warrant new agency action, as well as to assess the significance of that problem. The problems that today's standards address are as follows:

(1) There are external benefits resulting from improved energy efficiency of EPSs that are not captured by the users of such equipment. These benefits include externalities related to environmental protection and energy security that are not reflected in energy prices, such as reduced emissions of greenhouse gases. DOE attempts to quantify some of the external benefits through use of Social Cost of Carbon values.

In addition, DOE has determined that today's regulatory action is an "economically significant regulatory action" under section 3(f)(1) of Executive Order 12866. Accordingly, section 6(a)(3) of the Executive Order requires that DOE prepare a regulatory impact analysis (RIA) on today's rule and that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) review this rule. DOE presented to OIRA for review the draft rule and other documents prepared for this rulemaking, including the RIA, and has included these documents in the rulemaking record. The assessments prepared pursuant to Executive Order 12866 can be found in the technical support document for this rulemaking.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281 (Jan. 21, 2011)). EO 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, DOE believes that today's final rule is consistent with these principles, including the requirement that, to the extent permitted by law, benefits justify costs and that net benefits are maximized.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, and a final regulatory flexibility analysis (FRFA) for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (*http://energy.gov/gc/office-general-counsel*).

For manufacturers of EPSs, the Small Business Administration (SBA) has set a size threshold, which defines those entities classified as "small businesses" for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. 65 FR 30836, 30848 (May 15, 2000), as amended at 65 FR 53533, 53544 (Sept. 5, 2000) and codified at 13 CFR part 121.The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *http://www.sba.gov/content/summary-size-standards-industry*. EPS manufacturing is classified under NAICS 335999, "All Other Miscellaneous Electrical Equipment and Component Manufacturing." The SBA sets a threshold of 500 employees or less for an entity to be considered as a small business for this category.

As discussed in the March 2012 NOPR, DOE was unable to identify any EPS ODMs with domestic manufacturing. Information obtained from manufacturer interviews and DOE's research; indicate that all EPS manufacturing takes place abroad. DOE notes that it also sought comment on this issue. While DOE received comments from small businesses application manufacturers who import EPSs (see discussion in J.4), DOE did not receive any comments from any small business EPS ODMs or any comments challenging the view that all EPS manufacturing is conducted abroad. Since DOE was not able to find any small EPS ODMs, DOE certifies that today's final rule will not have a significant impact on a substantial number of small entities and that a regulatory flexibility analysis is not required.

C. Review Under the Paperwork Reduction Act

Manufacturers of EPSs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for EPSs, including any amendments adopted for those test procedures (76 FR 12422 (March 7, 2011). DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including Class-A EPSs. (cite 429.37) DOE will modify the certification requirements specific to non-class A EPSs (multiple-voltage and high-voltage) in a separate certification rulemaking prior to the effective date for the standards prescribed in today's rule. The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. See 10 CFR Part 1021, App. B, B5.1(b); 1021.410(b) and Appendix B, B(1)–(5). The rule fits within this category of actions because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this rule. DOE's CX determination for this rule is available at *http://cxnepa.energy.gov/*.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism." 64 FR 43255 (Aug. 10, 1999) imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of today's final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a

rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/gc/office-general-counsel.*

DOE has concluded that this final rule would likely require expenditures of $100 million or more on the private sector. Such expenditures may include: (1) Investment in research and development and in capital expenditures by EPS manufacturers in the years between the final rule and the compliance date for the new standards, and (2) incremental additional expenditures by consumers to purchase higher-efficiency EPSs, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the final rule. 2 U.S.C. 1532(c). The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of the notice of final rulemaking and the "Regulatory Impact Analysis" chapter of the final rule TSD respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. 2 U.S.C. 1535(a). DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(d), (f), and (o), 6313(e), and 6316(a), today's final rule would establish energy conservation standards for EPSs that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in the "Regulatory Impact Analysis" chapter of the final rule TSD.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that today's regulatory action, which sets forth energy conservation standards for EPSs, is not a significant energy action because the standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on the final rule.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are "influential scientific information," which the Bulletin defines as scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions. 70 FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective

criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The "Energy Conservation Standards Rulemaking Peer Review Report" dated February 2007 has been disseminated and is available at the following Web site: *www1.eere.energy.gov/buildings/appliance_standards/peer_review.html.*

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, and Small businesses.

Issued in Washington, DC, on February 3, 2014.

David T. Danielson,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE amends part 430 of chapter II, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by:

■ a. Redesignating paragraphs (a), (b), and (c) in the definition for *Annual fuel utilization efficiency* as paragraphs (1), (2), and (3), respectively;

■ b. Adding in alphabetical order definitions for *Basic-voltage external power supply* and *Direct operation external power supply;*

■ c. Redesignating paragraphs (a), (b), (c), and (d) in the definition for *Furnace* as paragraphs (1), (2), (3), and (4), respectively;

■ d. Adding in alphabetical order definitions for *Indirect operation external power supply* and *Low-voltage external power supply;*

■ e. Redesignating paragraphs (a), (b), and (c) in the definition for *Water heater* as paragraphs (1), (2), and (3), respectively.

The additions read as follows:

§ 430.2 Definitions.

* * * * *

Basic-voltage external power supply means an external power supply that is not a low-voltage external power supply.

* * * * *

Direct operation external power supply means an external power supply that can operate a consumer product that is not a battery charger without the assistance of a battery.

* * * * *

Indirect operation external power supply means an external power supply that cannot operate a consumer product that is not a battery charger without the assistance of a battery as determined by the steps in paragraphs (1)(i) through (v) of this definition:

(1) If the external power supply (EPS) can be connected to an end-use consumer product and that consumer product can be operated using battery power, the method for determining whether that EPS is incapable of operating that consumer product directly is as follows:

(i) If the end-use product has a removable battery, remove it for the remainder of the test and proceed to the step in paragraph (1)(v) of this definition. If not, proceed to the step in paragraph (1)(ii).

(ii) Charge the battery in the application via the EPS such that the application can operate as intended before taking any additional steps.

(iii) Disconnect the EPS from the application. From an off mode state, turn on the application and record the time necessary for it to become operational to the nearest five second increment (5 sec, 10 sec, etc.).

(iv) Operate the application using power only from the battery until the application stops functioning due to the battery discharging.

(v) Connect the EPS first to mains and then to the application. Immediately attempt to operate the application. If the battery was removed for testing and the end-use product operates as intended, the EPS is not an indirect operation EPS and paragraph 2 of this definition does not apply. If the battery could not be removed for testing, record the time for the application to become operational to the nearest five second increment (5 seconds, 10 seconds, etc.).

(2) If the time recorded in paragraph (1)(v) of this definition is greater than the summation of the time recorded in paragraph (1)(iii) of this definition and five seconds, the EPS cannot operate the application directly and is an indirect operation EPS.

* * * * *

Low-voltage external power supply means an external power supply with a nameplate output voltage less than 6 volts and nameplate output current greater than or equal to 550 milliamps.

* * * * *

■ 3. Section 430.3 is amended by revising paragraph (p) introductory text and adding paragraph (p)(3) to read as follows:

* * * * *

§ 430.3 Materials incorporated by reference.

* * * * *

(p) *U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy.* Resource Room of the Building Technologies Program, 950 L'Enfant Plaza SW., 6th Floor, Washington, DC 20024, 202–586–2945, (Energy Star materials are also found at *http://www.energystar.gov.*)

* * * * *

(3) International Efficiency Marking Protocol for External Power Supplies, Version 3.0, September 2013, IBR approved for § 430.32.

* * * * *

■ 4. Section 430.32 is amended by revising paragraph (w) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(w) *External power supplies.* (1)(i) Except as provided in paragraphs (w)(2) and (5) of this section, all Class A external power supplies manufactured on or after July 1, 2008, shall meet the following standards:

Active Mode	
Nameplate output	Required efficiency (decimal equivalent of a percentage)
Less than 1 watt	0.5 times the Nameplate output.

Active Mode	
Nameplate output	Required efficiency (decimal equivalent of a percentage)
From 1 watt to not more than 51 watts	The sum of 0.09 times the Natural Logarithm of the Nameplate Output and 0.5.
Greater than 51 watts	0.85.
Not more than 250 watts	0.5 watts.

(ii) Except as provided in paragraphs (w)(5), (w)(6), and (w)(7) of this section, all direct operation external power supplies manufactured on or after February 10, 2016, shall meet the following standards:

Single-Voltage External AC-DC Power Supply, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	≤ 0.100
1 W $< P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	≤ 0.100
49 W $< P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500

Single-Voltage External AC-DC Power Supply, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	≤ 0.100
1 W $< P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	≤ 0.100
49 W $< P_{out} \leq 250$ W	≥ 0.870	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500

Single-Voltage External AC-AC Power Supply, Basic-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	≤ 0.210
1 W $< P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	≤ 0.210
49 W $< P_{out} \leq 250$ W	≥ 0.880	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500

Single-Voltage External AC-AC Power Supply, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	≤ 0.210
1 W $< P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	≤ 0.210

49 W < P_{out} ≤ 250 W	≥ 0.870	≤ 0.210
P_{out} > 250 W	≥ 0.875	≤ 0.500
Multiple-Voltage External Power Supply		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** *(expressed as a decimal)*	**Maximum Power in No-Load Mode [W]**
P_{out} ≤ 1 W	≥ 0.497 × P_{out} + 0.067	≤ 0.300
1 W < P_{out} ≤ 49 W	≥ 0.075 × ln(P_{out}) + 0.561	≤ 0.300
P_{out} > 49 W	≥ 0.860	≤ 0.300

(2) A Class A external power supply shall not be subject to the standards in paragraph (w)(1)(i) of this section if the Class A external power supply is—

(i) Manufactured during the period beginning on July 1, 2008, and ending on June 30, 2015, and

(ii) Made available by the manufacturer as a service part or a spare part for an end-use product—

(A) That constitutes the primary load; and

(B) Was manufactured before July 1, 2008.

(3) The standards described in paragraph (w)(1) of this section shall not constitute an energy conservation standard for the separate end-use product to which the external power supply is connected.

(4) Any external power supply subject to the standards in paragraph (w)(1) of this section shall be clearly and permanently marked in accordance with the International Efficiency Marking Protocol for External Power Supplies (incorporated by reference; see § 430.3), published by the U.S. Department of Energy.

(5) *Non-application of no-load mode requirements.* The no-load mode energy efficiency standards established in paragraph (w)(1) of this section shall not apply to an external power supply manufactured before July 1, 2017, that—

(i) Is an AC-to-AC external power supply;

(ii) Has a nameplate output of 20 watts or more;

(iii) Is certified to the Secretary as being designed to be connected to a security or life safety alarm or surveillance system component; and

(iv) On establishment within the External Power Supply International Efficiency Marking Protocol, as referenced in the "Energy Star Program Requirements for Single Voltage External Ac-Dc and Ac-Ac Power Supplies" (incorporated by reference, see § 430.3), published by the Environmental Protection Agency, of a distinguishing mark for products described in this clause, is permanently marked with the distinguishing mark.

(6) An external power supply shall not be subject to the standards in paragraph (w)(1) of this section if it is a device that requires Federal Food and Drug Administration (FDA) listing and approval as a medical device in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)).

(7) A direct operation, AC–DC external power supply with nameplate output voltage less than 3 volts and nameplate output current greater than or equal to 1,000 milliamps that charges the battery of a product that is fully or primarily motor operated shall not be subject to the standards in paragraph (w)(1)(ii) of this section.

* * * * *

[FR Doc. 2014–02560 Filed 2–7–14; 8:45 am]

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 106 and 107

Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. FDA–1995–N–0036 (formerly 95N–0309)]

RIN 0910–AF27

Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is revising our infant formula regulations to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

DATES: *Effective date:* This interim final rule is effective July 10, 2014.

Comment date: Interested persons may submit either electronic or written comments on this interim final rule by March 27, 2014.

Paperwork Reduction Act date: Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 12, 2014, (see the "Paperwork Reduction Act of 1995" section of this document). The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of July 10, 2014.

ADDRESSES: Submit either electronic or written comments on the interim final rule to the addresses in this **ADDRESSES** section. To ensure that comments on information collection are received, the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–5806. All comments received must include the Agency name, Docket No. FDA–1995–N–0036, and RIN number 0910–AF27 for this rulemaking. You may submit comments, identified by Docket No. FDA–1995–N–0036 (formerly 95N–0309) and/or RIN number RIN 0910–AF27, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–1995–N–0036 (formerly 95N–0309) and RIN 0910–AF27 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benson M. Silverman, Office of Nutrition, Labeling, and Dietary Supplements (HFS–850), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 240–402–1450.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Interim Final Rule

FDA is issuing this interim final rule to fulfill the statutory mandate set forth in section 412 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a) for the Secretary of Health and Human Services (the Secretary), and by delegation FDA, to establish requirements for quality factors for infant formulas and good manufacturing practices, including quality control procedures. The requirements in this interim final rule will prevent the manufacture of adulterated infant formula and ensure that the nutrients in the infant formula are present in a form that is bioavailable and safe. Congress passed the Infant Formula Act of 1980 (the Infant Formula Act) (Pub. L. 96–359), which amended the FD&C Act to include section 412. In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99–570) (the 1986 amendments), amended section 412 of the FD&C Act to address concerns related to the sufficiency of quality control testing, current good manufacturing practice (CGMP), recordkeeping, and recall requirements for infant formula. The requirements in this interim final rule improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula.

We previously implemented certain of the provisions in the Infant Formula Act and 1986 amendments. This interim final rule implements the remaining provisions of the 1986 amendments, including provisions for CGMPs and quality factor requirements.

Summary of Legal Authority

Section 412 of the FD&C Act provides FDA with the authority to establish requirements for quality factors, CGMPs, quality control procedures, registration, submission, notification, and records and reports. Specifically, FDA's authority to establish requirements for quality factors is derived from section 412(b)(1) of the FD&C Act. The authority to establish requirements for CGMPs and quality control procedures derives from section 412(b)(2) and (b)(3) of the FD&C Act. FDA also has authority to establish requirements for registration, submission, and notification under section 412(c) and (d) of the FD&C Act, respectively. Finally, a number of specific authorities in section 412 of the FD&C Act provide FDA with authority to establish requirements for records and reports, e.g., section 412(b)(4)(A) related to record retention for good manufacturing practices and quality control procedures, audits and complaints. Moreover, section 701(a) of the FD&C Act (21 U.S.C. 371(a)), when coupled with other provisions of section 412 of the FD&C Act, provides FDA with the authority to issue records requirements that are necessary for the efficient enforcement of section 412.

Sections 701(a) and 402 of the FD&C Act (21 U.S.C. 371(a) and 342) provide additional authority to establish requirements to prevent adulteration.

Summary of the Major Provisions of the Interim Final Rule

Current Good Manufacturing Practice

This interim final rule issues comprehensive CGMP requirements for

the manufacture of infant formula by establishing a framework in which specific process and control decisions are assigned to the formula manufacturer; i.e., it specifies the result to be achieved and does not prescriptively mandate how the manufacturer must achieve the result.

Under § 106.6, the interim final rule requires manufacturers to implement a system of production and in-process controls that covers all stages of processing. The system must be set out in a written plan or set of procedures that includes establishment of specifications and corrective action plans, documented reviews and material disposition decisions for articles not meeting a specification, and the quarantine of any article that fails to meet a specification pending completion of a documented review and material disposition decision.

The interim final rule also includes specific controls to prevent adulteration by workers (§ 106.10), facilities (§ 106.20), equipment or utensils (§ 106.30), automatic (mechanical or electronic) equipment (§ 106.35), and ingredients, containers, and closures (§ 106.40). Under § 106.50, manufacturers are required to prepare and follow a written master manufacturing order that establishes controls and procedures for the production of an infant formula. In addition, controls are specified to prevent adulteration during packaging and labeling (§ 106.60) and on the release of finished infant formula (§ 106.70). The interim final rule also requires that infant formula be coded with a sequential number that permits identification of the product including the location where it was packed and tracing of all stages of manufacture (§ 106.80).

Controls are also required to prevent adulteration of infant formula from microorganisms (§ 106.55). Because powdered infant formulas are not sterile products, the interim final rule requires testing of representative samples of powdered infant formula at the final product stage, before distribution, and establishes values for two microorganisms, *Cronobacter* spp. and *Salmonella* spp.

Quality Control Procedures

The interim final rule revises FDA's existing infant formula quality control procedures regulations to implement the 1986 amendments. Under § 106.91, the revised regulations require in-process and final product testing of infant formula to ensure that all required and added nutrients are present at appropriate levels. The revised regulations also require comprehensive stability testing for new infant formula and routine stability for subsequently produced infant formula.

Audits

The interim final rule includes requirements for audits under §§ 106.90, 106.92, and 106.94. Regularly scheduled audits of CGMP and quality control procedures must be conducted according to a written audit plan at a frequency required to ensure compliance with the provisions of the interim final rule.

Quality Factors

The interim final rule identifies two infant formula quality factors, normal physical growth and sufficient biological quality of the formula's protein component, and establishes requirements for the two quality factors in § 106.96. Under the interim final rule, quality factors are defined as those factors necessary to demonstrate the bioavailability and safety of a formula, including the bioavailability of individual nutrients, to ensure healthy growth (§ 106.3).

To establish that an infant formula supports normal physical growth, the interim final rule requires under § 106.96(b) that a manufacturer conduct a growth monitoring study (GMS) of the formula (unless the formula qualifies for an exemption). To establish biological protein quality, the interim final rule requires under § 106.96(f) that a manufacturer conduct a Protein Efficiency Ratio (PER) rat bioassay.

The interim final rule's quality factor requirements apply to *all* infant formulas. Because, prior to this interim final rule, there were no established quality factors and no quality factor requirements, a formula manufacturer was not required to demonstrate to FDA that the formula supports normal physical growth or that its protein was of sufficient biological quality. Therefore, we provide a more flexible means for a manufacturer of a formula that is "not new" (i.e., a currently marketed or previously marketed formula) to demonstrate satisfaction of the two quality factors (§ 106.96(i)). The more flexible standards will allow manufacturers, as appropriate, to rely on existing scientific data and information and to voluntarily submit quality factor data and information on a specific infant formula formulation to FDA for evaluation.

Records and Reports

The majority of the interim final rule's records and reports provisions are designed to support or otherwise help to actualize other interim final rule requirements. Manufacturers of infant formula are required to establish and maintain various records that help demonstrate compliance with the quality factor, CGMP, quality control procedure, registration, submission, and notification requirements. For example, the interim final rule includes a requirement (§ 106.100(e)(5)(ii)) that a manufacturer establish and maintain records of the microbiological testing of infant formula required under § 106.55.

Registration, Submission, and Notification Requirements

The registration requirements under § 106.110 of the interim final rule require infant formula manufacturers to provide FDA with up-to-date information about firms producing infant formula for U.S. distribution. Furthermore, the notification requirements under §§ 106.120 and 106.121 require an infant formula manufacturer to submit scientific data and information to FDA to demonstrate that a new infant formula contains all required nutrients, is produced consistent with the interim final rule's CGMP and quality control requirements, and meets established quality factors. The submission provisions also permit a manufacturer of infant formula for export only to make an alternative submission that provides assurances that the relevant export provisions of the FD&C Act are satisfied and that the manufacturer has established adequate controls to ensure that these formulas are actually exported.

Costs and Benefits

The estimated cost of the interim final rule is $7.29 million in the first year and $4.06 million in subsequent years. The estimated benefit to public health from this interim final rule is $10.00 million annually, resulting in total net benefits of $2.71 million in the first year and $5.94 million in subsequent years.

BENEFIT AND COST OVERVIEW

[In millions]

	Benefits	Costs	Net Benefits
Total First Year	$10.00	$7.29	$2.71
Annual Total After the First Year	$10.00	$4.06	$5.94

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I. Background

The Infant Formula Act amended the FD&C Act to include section 412. This law was intended to improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. In 1982, FDA adopted infant formula recall procedures in subpart D of part 107 (21 CFR part 107, subpart D) of its regulations (47 FR 18832, April 30, 1982), and infant formula quality control procedures in subpart B of part 106 (21 CFR part 106, subpart B) (47 FR 17016, April 20, 1982). In 1985, FDA further implemented the Infant Formula Act by establishing subparts B, C, and D in part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula, respectively (50 FR 1833, January 14, 1985; 50 FR 48183, November 22, 1985; and 50 FR 45106, October 30, 1985).

In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99–570) (the 1986 amendments), amended section 412 of the FD&C Act to address concerns that had been expressed by Congress and consumers about the Infant Formula Act and its implementation related to the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. The 1986 amendments: (1) Provide that an infant formula is deemed to be adulterated if it fails to provide certain required nutrients, fails to meet quality factor requirements established by the Secretary (and, by delegation, FDA), or if it is not processed in compliance with the CGMP and quality control procedures established by the Secretary; (2) require the Secretary to issue regulations establishing requirements for quality factors and CGMP, including quality control procedures; (3) require infant formula manufacturers to audit their operations regularly to ensure that those operations comply with CGMP and quality control procedure regulations; (4) require a manufacturer to make a submission to FDA when there is a major change in an infant formula or a change that may affect whether the formula is adulterated; (5) specify the required nutrient quality control testing for each batch of infant formula; (6) modify the infant formula recall requirements; and (7) authorize the Secretary to establish requirements for records retention, including records necessary to demonstrate compliance with CGMP and quality control procedures. In 1989, the Agency implemented the provisions on recalls (sections 412(f) and (g) of the FD&C Act) by establishing subpart E in part 107 (54 FR 4006, January 27, 1989). In 1991, the Agency implemented the provisions on records and record retention requirements by revising § 106.100 (56 FR 66566, December 24, 1991).

On July 9, 1996, FDA published a notice of proposed rulemaking (the 1996 proposal) to implement the remaining provisions of the 1986 amendments (61 FR 36154). Specifically, FDA proposed to amend the infant formula regulations in parts 106 and 107 to: (1) Establish good manufacturing practices, including microbiological testing, to minimize production of adulterated infant formula; (2) revise the quality control procedures in part 106 to ensure that an infant formula contains the level of nutrients necessary to support infant growth and development, both when the formula enters commerce and throughout its shelf life; (3) specify the audit procedures necessary to ensure that operations comply with CGMP and quality control procedure regulations; (4) establish requirements for quality factors to ensure that the required nutrients will be in a bioavailable form; (5) establish batch and good manufacturing recordkeeping requirements; (6) specify the submission requirements for registration and notification to the Agency before the introduction of an infant formula into interstate commerce; and (7) update part 107 to reflect the 1986 amendments and the November 1992 reorganization of the Center for Food Safety and Applied Nutrition (CFSAN).

FDA initially opened the comment period for the 1996 proposal for 90 days and subsequently extended it upon request for another 60 days (61 FR 49714, September 23, 1996).

Following publication of the proposed rule in September 1996, FDA convened three meetings of FDA's Food Advisory Committee (FAC) or subcommittees of the FAC to address issues related to the regulation of infant formula. On April 4 and 5, 2002, the FAC met to discuss general scientific principles related to quality factors for infant formula. The FAC also discussed the scientific issues related to the generalization of findings from a clinical study using preterm infant formula consumed by preterm infants to a different formula in a different population (a term infant formula intended for use by term infants). At a meeting on November 18 and 19, 2002, the Infant Formula Subcommittee (IFS) of the FAC discussed the scientific issues and principles involved in assessing and evaluating whether a "new" infant formula supports normal physical growth in infants when consumed as a sole source of nutrition. Finally, the Contaminants and Natural Toxicants Subcommittee (CNTS) of the FAC met on March 18 and 19, 2003, and discussed the scientific issues and principles involved in assessing and evaluating *Enterobacter sakazakii* contamination in powdered infant formula, risk reduction strategies based on available data, and research questions and priorities. (The organism *E. sakazakii* was reclassified in 2008 to a new genus, *Cronobacter* spp.) (Ref. 1).

In the **Federal Register** of April 28, 2003 (68 FR 22341) (the 2003 reopening), FDA reopened the comment period for the proposed rule to update comments generally and to receive new information based on the three FAC meetings held in 2002 and 2003. FDA specifically requested comment on the following issues related to these meetings: (1) Whether there is a need for a microbiological requirement for *E. sakazakii*, and if so, what requirement the Agency should consider to ensure safety and whether a stricter standard was needed for powdered infant formula to be consumed by premature and newborn infants; (2) what changes, if any, in the proposed microbiological requirements would be needed to ensure the safety of powdered infant formula to which microorganisms are intentionally added; (3) which provisions in the proposed rule would require changes to manufacturers' current activities, and a request for information on the types of control systems used to separate materials and types of air filtration systems and associated costs of making changes in each case; (4) current quality control activities by manufacturers related to validation of automated systems and FDA's proposed validation requirements; (5) current frequency and conditions of calibration of instruments and controls by manufacturers and the adequacy of such procedures; (6) quality factor issues, including sufficiency of protein quality and normal physical growth as quality factors, and when clinical growth studies are required for a new or reformulated infant formula; which growth reference should be the standard of comparison for infant growth; and duration of study and enrollment age; and (7) removal of the reference to Institutional Review Board (IRB) review and informed consent from the proposed rule as the requirements are now codified in 21 CFR parts 50 and 56, and removal of the other clinical study protocol provisions from the proposed rule for consideration in a future guidance document.

Interested persons were originally given until June 27, 2003, to comment on these issues and the 1996 proposal. However, in response to a request, the comment period was extended to August 26, 2003 (68 FR 38247, June 27, 2003).

Based on three reports published after the 2003 reopening, FDA again reopened the comment period on August 1, 2006 (71 FR 43392) (the 2006 reopening), for 45 days to accept comment on a limited set of issues related to these reports. Two reports address microbiological standards for *E. sakazakii* and other microbes; the third report addresses, in part, clinical studies as a means to assess the growth and development of infants. The reports addressing microbiological standards are products of a series of expert consultations related to the efforts of the Codex Committee on Food Hygiene (CCFH) of the Codex Alimentarius Commission to update the 1979 Recommended International Code of Hygienic Practice for Foods for Infants and Children (the 1979 Code). These reports ("*Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula: Meeting Report" (the 2004 FAO/WHO Report) (Ref. 2) and "*E. sakazakii* and *Salmonella* spp. in Powdered Infant Formula" (the 2006 FAO/WHO Report) (Ref. 3)) were issued by the Food and Agriculture Organization of the United Nations, World Health Organization (WHO), in 2004 and 2006 and provide scientific advice concerning *E. sakazakii*, *Salmonella spp*, and other microorganisms in powdered infant formula. The third report is from the Committee on the Evaluation of the Addition of Ingredients New to Infant Formula, which the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) convened at the request of FDA and Health Canada, FDA's Canadian counterpart. The purpose of the report was, in part, to evaluate the performance of a new infant formula. The committee made several recommendations regarding growth studies, including the recommendation that "Growth studies should include precise and reliable measurements of weight and length velocity and head circumference. Duration of measurements should cover at least the period when infant formula remains the sole source of nutrients in the infant diet." (Ref. 4, p. 108).

In reopening the comment period in August 2006, FDA requested comment on the following issues:

- Whether FDA should require a microbiological standard for *E. sakazakii* for powdered infant formula of negative in 30 x 10 gram (g) samples;
- Whether FDA should require microbiological standards for aerobic plate count, coliforms, fecal coliforms, *Listeria monocytogenes*, *Bacillus cereus*, and *Staphylococcus aureus;*

- Whether FDA should require measurements of healthy growth beyond the two proposed quality factors of normal physical growth (as measured by body weight, recumbent length, head circumference, and average daily weight increment) and protein quality;
- Whether FDA should require a measure for body composition as an indicator of normal physical growth, and if so, what measure; and
- Whether FDA should require that the duration for a clinical study, if required, be no less than 15 weeks, and commence when infants are no older than 2 weeks of age.

II. Highlights of the Interim Final Rule and Summary of Significant Changes Made to the Proposed Rule

The highlights of this interim final rule are as follows:

- FDA is establishing CGMP requirements for the production of nonexempt infant formula. FDA is also clarifying the current requirements related to the validation of manufacturing systems and the establishment of specifications in the manufacture of infant formula.
- FDA is establishing requirements for microbiological quality to prevent adulteration of powdered infant formula.
- FDA is establishing requirements for quality factors to provide assurance that, as a sole source of nutrition, an infant formula supports infants' healthy growth. These provisions include a requirement to conduct an adequate and well-controlled growth monitoring study to measure physical growth and exemptions from the requirement to conduct such a study.
- FDA is establishing requirements for recordkeeping and reports that, where possible, reduce redundancy.

III. Legal Authority

FDA's authority to issue regulations that establish requirements for quality factors, current good manufacturing practices, quality control procedures, registration, submission, notification, and records and reports is derived from section 412 of the FD&C Act. FDA also relies on other sections of the FD&C Act, including sections 701(a) and 402 (21 U.S.C. 371(a) and 342). The regulations in this interim final rule are consistent with FDA's explicit statutory mission, which is, in part, to protect the public health by ensuring that foods (including infant formula) are safe, wholesome, sanitary, and properly labeled (section 903(b)(2)(A) of the FD&C Act (21 U.S.C. 393(b)(2)(A))). The regulations are also consistent with the overall purpose of section 412 of the FD&C Act (*see* Pub. L. 96–359, 94 Stat. 1190, 1190 (1980) (stating the purpose of the Infant Formula Act is to provide for the "safety and nutrition" of infant formula)).

FDA's authority to establish requirements for quality factors is explicit in section 412(b)(1) of the FD&C Act, which states that the "Secretary shall by regulation establish requirements for quality factors." Infant formulas that are not in compliance with the quality factor requirements are adulterated under section 412(a)(2) of the FD&C Act. In section IV of this interim final rule FDA defines "quality factors," and in section VIII FDA establishes specific quality factor requirements.

Similarly, FDA's authority to establish current good manufacturing practices and quality control procedure requirements is explicit in section 412(b)(2) of the FD&C Act. Section 412(b)(2) of the FD&C Act specifies certain overarching requirements that must be included as part of CGMP and quality control procedure requirements. Specifically, the section states that the "Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula . . . is manufactured in a manner designed to prevent adulteration of the infant formula." Infant formulas that are not in compliance with the CGMP and quality control procedure requirements are adulterated under section 412(a)(3) of the FD&C Act. In addition, the failure to comply with certain CGMP requirements will result in the infant formula being adulterated under sections 402(a)(1), (a)(2), (a)(3), or (a)(4) of the FD&C Act. Although Congress has identified specific provisions that must be included as CGMP and quality control procedure requirements (see section 412(b)(2) and (b)(3) of the FD&C Act), it did not prescribe all such requirements. Rather, Congress left a gap for FDA to prescribe, by regulation, such other practices and procedures necessary to ensure the nutrient content of infant formula and prevent adulteration under section 412(b)(2) of the FD&C Act.

In addition, FDA has explicit authority under sections 412(c), (d), and (e) of the FD&C Act to establish registration, submission, and notification requirements, respectively. Section 412(c)(1)(A) of the FD&C Act states that no person may introduce a new infant formula into interstate commerce, unless the person has "registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacturer such infant formula." The registration requirements in the interim final rule set forth the information that must be included in a new infant formula registration sent to FDA.

Further, the interim final rule sets forth the information that must be included in a new infant formula submission to FDA. Section 412(d) of the FD&C Act requires that a manufacturer make an infant formula submission and describes the type of information that must be included in such submission. For example, section 412(d)(1)(A) of the FD&C Act requires that the submission include the quantitative formulation of the formula. Additionally, section 412(d)(1)(C) of the FD&C Act requires, in part, assurances that the infant formula will not be marketed unless it meets the requirements of section 412(b)(1) of the FD&C Act (quality factor requirements). Section 412(d)(1)(D) of the FD&C Act requires assurances that the formula will not be marketed unless the processing of the formula complies with section 412(b)(2) of the FD&C Act (the CGMP and quality control procedure requirements). The interim final rule prescribes requirements for the assurances required by these sections of the FD&C Act.

The notification requirements in the interim final rule describe when a notification must be provided to FDA, as required by section 412(e) of the FD&C Act. Section 412(e) of the FD&C Act sets forth the circumstances in which a manufacturer must notify FDA that an infant formula processed by the manufacturer has left an establishment under the manufacturer's control and may be adulterated or misbranded.

FDA also has authority to establish requirements for records under section 412(b)(4)(A) of the FD&C Act. This interim final rule includes record requirements for CGMP and quality control procedures and for the conduct of audits. For example, under section 412(b)(4)(A)(i) of the FD&C Act, FDA has authority to establish recordkeeping requirements necessary to demonstrate compliance with CGMP and quality control procedure requirements, including records containing the results of all testing designed to prevent the adulteration of infant formula. Thus, FDA is establishing requirements in this interim final rule for manufacturers to make and retain records that include complete information relating to the production and control of each production aggregate (for discussion of this term *see* section IV.C.1 of this document) of infant formula to ensure

compliance with the CGMP and quality control procedure requirements related to the production aggregate. Specifically, § 106.100(e) requires manufacturers to make and retain records that include complete information relating to the production and control of the production aggregate. Information about the processing of the production aggregate is important to the manufacturer, which must ensure that it is producing the formula it intends to produce under the master manufacturing order. In addition, if a problem arises from a particular production aggregate of formula, such records will assist the manufacturer and FDA in identifying the source of the problem and what action may be necessary to correct it. For example, § 106.100(e)(3) requires documentation of the monitoring at any point, step, or stage in the production process where control is deemed necessary to prevent adulteration.

Moreover, FDA has authority to establish record requirements under other provisions of section 412 of the FD&C Act, as well as section 701(a) of the FD&C Act. For example, as is discussed in greater detail in section VIII, it is necessary for manufacturers to create records pertaining to a growth monitoring study in order to determine whether their infant formula meets the quality factor requirement of normal physical growth established under section 412(b)(1) of the FD&C Act. It is also necessary for the enforcement of section 412(a)(2) of the FD&C Act, with respect to meeting quality factor requirements, for FDA to require records pertaining to a growth monitoring study, when such a study is required. Without such records, FDA cannot determine whether the quality factor requirements have been met. Additionally, FDA has authority under section 701(a) of the FD&C Act, when coupled with the specific authorities granted to FDA under section 412 of the FD&C Act, to establish record requirements that are necessary for the efficient enforcement of the FD&C Act.

IV. General Comments and Subpart A—General Provisions

During the three periods provided for comments, FDA received a number of comments in response to the proposed rule. Some of the comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions and requested revisions. A few comments addressed issues outside the scope of the proposal and will not be discussed in this document. To make it easier to identify comments and FDA's responses to the comments, the word "Comment" will appear in parentheses before the description of the comment, and the word, "Response" will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was submitted. Comments generally are not distinguished by year of receipt.

A. General Comments

The general comments discussed in this section are those that addressed the rule in its entirety.

(Comment 1) One comment stated that many provisions of the infant formula proposal are "overly redundant" with other FDA laws and regulations, such as the food CGMP and food additive regulations. These redundancies include personnel requirements and the permitted use of food ingredients and food contact materials. The comment claims that these redundancies do not provide the public with greater protection, but serve only to create unnecessary confusion in those plants manufacturing both infant formulas and similar products not intended for use by infants. The comment noted that FDA's stated intent in promulgating the food CGMP regulations was to have those regulations function as "umbrella" regulations, to which FDA would add additional regulations targeted at specific industries.

(Response) As stated in the proposed rule, the CGMP requirements for infant formula are based, in part, on FDA's existing regulations concerning CGMP for foods (61 FR 36154 at 36157). Infant formulas are food, and thus, the Agency would expect that certain CGMP requirements for infant formula would parallel the CGMP provisions in part 110 (21 CFR part 110).

FDA disagrees, however, that many provisions of the infant formula rule are overly redundant with other FDA laws and regulations. The food CGMP regulations (part 110) predate the 1986 amendments. Thus, Congress was aware of these regulations at the time of the 1986 amendments when it established an explicit mandate for infant formula CGMP. By mandating that FDA establish good manufacturing practices, including quality control procedures, Congress recognized that requirements in addition to the food CGMP were necessary for infant formula. The CGMP regulations established by this interim final rule implement Congress' express mandate. As noted, section 412(b)(2)(A) of the FD&C Act specifically mandates that FDA establish CGMP for infant formula: "The Secretary shall, by regulation, establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with [section 412] and is manufactured in a manner designed to prevent adulteration of the infant formula." In addition, section 412(a)(3) of the FD&C Act provides that an infant formula is deemed to be adulterated if "the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary" under section 412(b)(2). This provision of section 412 of the FD&C Act underscores the Congressional determination that product-specific CGMP requirements are necessary for infant formula.

Moreover, the purpose of section 412 of the FD&C Act is to ensure product safety for the vulnerable population that consumes infant formula. To this end, FDA may include CGMP requirements in this interim final rule that are the same or similar to those found in 21 CFR part 110 for foods in general. FDA has included in this interim final rule the part 110 requirements that are common to most or all infant formula manufacturing. The Agency recognizes that there may be aspects of infant formula manufacturing operations for which certain provisions in part 110 apply, but that FDA did not determine to be common to most infant formula manufacturing operations. Infant formula manufacturers are responsible for understanding and following all of the regulations that govern their products even if the regulations are not in parts 106 and 107.[1] Thus, a manufacturer is subject to the regulations in part 110 in addition to the regulations in part 106. To the extent that the regulations conflict, the infant formula manufacturer must comply with part 106.

[1] FDA notes that the FDA Food Safety Modernization Act (FSMA) creates new requirements with respect to food safety and requires FDA to issue certain regulations. For example, section 103 of FSMA requires FDA to issue regulations establishing science-based minimum standards for certain food facilities to conduct a hazard analysis, document hazards, implement preventive controls, and document implementation of such preventive controls (Pub. L. 111–353, 124 Stat. 3885 (2011)). The purpose of this interim final rule is not to implement the requirements of FSMA. Any additional requirements in the rulemakings implementing FSMA that may apply to infant formula will be addressed in those rulemakings.

In addition, FDA may include CGMP requirements in this interim final rule concerning the use of lawful ingredients and food packaging materials. Section 106.40(a) states that only substances that are safe and suitable under the applicable food safety provisions of the FD&C Act may be used in infant formulas. Section 106.40(b) requires that packaging material that comes in contact with infant formula be composed of substances that are safe and lawful for such use. FDA disagrees such requirements are "overly redundant." The statute contains express authority to establish by regulation CGMP requirements for infant formula to prevent adulteration, in general (*see* section 412(b)(2)(A) of the FD&C Act) and to prevent adulteration of each production aggregate of infant formula, specifically (*see* section 412(b)(2)(B)(iii) of the FD&C Act). The use of ingredients in the formula, and of substances in food packaging materials that would come into contact with the formula, that are safe and lawful is important to ensuring that each production aggregate of infant formula is not adulterated. Sections 106.40(a) and (b) help to ensure that appropriate manufacturing processes are in place such that only safe and lawful food ingredients and food packaging materials are used to manufacture infant formula, a food intended for consumption by a vulnerable population. These requirements are necessary to ensure the safety of all of the formula's ingredients and food packaging materials used in the manufacture of an infant formula to prevent adulteration of the infant formula. A failure to do so would result in the infant formula being deemed adulterated under section 412 of the FD&C Act.

For the reasons set forth previously in this document, the Agency is making no changes to the language set forth in the proposed rule in response to this comment.

(Comment 2) One comment stated that since the proposed rule was published, FDA's Center for Drug Evaluation and Research (CDER) announced a new initiative on August 21, 2002, "Pharmaceutical CGMP for the 21st Century: A Risk Based Approach" (Ref. 5) that involves significant examination and reevaluation of FDA's drug CGMP. The comment suggested that the infant formula CGMP may benefit from using this risk-based drug CGMP initiative as a model and that the infant formula industry partner with CFSAN in the same way that CDER and other FDA Centers are partnering with the industries they regulate.

(Response) In developing this interim final rule, FDA did consider the drug CGMPs and those for other FDA-regulated products. FDA has on many occasions held discussions with, solicited comments from, and partnered with the infant formula industry to work toward a risk-based philosophy that provides for process control that is scientifically validated, rather than on a system that is overly reliant on testing. In addition to the three FAC meetings described previously in this document, the Agency and the infant formula industry have worked collaboratively to provide input for the WHO expert consultation on testing for microorganisms of public health significance in powdered infant formula, and to provide input on the revision of the Codex hygienic practices for production of powdered infant formula. In addition, the Agency has provided opportunities for the public, including the infant formula industry, to communicate with FDA by reopening the comment period on the proposed rule on two occasions, and again by accepting comments upon publication of this interim final rule. Thus, this rulemaking has been a collaborative process that has resulted in a sound, risk-based approach to process control for infant formula manufacture.

An example of the Agency's risk-based approach is the resolution in the interim final rule of the requirements for microbiological testing. As discussed in more detail in section V, in the 1996 proposed rule, FDA proposed broad microbiological testing requirements for powdered formula. Upon further evaluation, the Agency determined that most of the pathogens originally proposed for testing have not been associated with infant formula. Instead, relying on the WHO risk assessment model set out in the 2006 FAO/WHO Report (Ref. 3), FDA determined that *Cronobacter* spp. (formerly classified as *E sakazakii*) and *Salmonella* spp. are the only two pathogens of concern for powdered infant formula. Thus, the interim final rule replaces the broad microbiological testing mandate in the proposal with more narrow, risk-based requirements.

(Comment 3) One comment asked FDA to acknowledge in the preamble to the final rule that under the FD&C Act and § 107.50(c) of the regulations, exempt infant formulas are not subject to the CGMP, quality control, and quality factor requirements of part 106. The comment identified some logistical issues associated with the application of quality factor requirements to exempt infant formulas. The comment also requested that FDA state in the preamble that during inspections of special infant formula manufacturing plants (referring to plants that manufacture exempt infant formula), the Agency will accept quality control activities other than those articulated in part 106 provided that the manufacturer documents those activities, demonstrates that the product meets the nutrient requirements of the FD&C Act, and manufactures the product in a manner designed to prevent adulteration. The comment stated that FDA should encourage manufacturers of exempt infant formula to comply voluntarily with part 106, where practical, because exempt formulas should be manufactured to a high standard of quality.

(Response) The regulations in § 107.50 pertaining to exempt infant formula were finalized in 1985 (50 FR 48183) prior to the 1986 amendments. As FDA explained in the 1996 proposal, the Agency intends to address, in a separate rulemaking, the exempt infant formula regulations and the effect of the 1986 amendments on exempt infant formulas (61 FR 36154 at 36201–36202). In the interim, FDA encourages exempt infant formula manufacturers to use the requirements in this interim final rule as guidance because infant formulas for use by infants with inborn errors of metabolism, low birth weight, or other unusual medical or dietary problems should conform to the same standards set forth in the requirements of this interim final rule applicable to formulas for healthy term infants, unless there is a medical, nutritional, scientific, or technological rationale for a deviation from such requirements. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice of availability for a draft guidance document that addresses the application of new part 106 to exempt infant formulas. Manufacturers are encouraged to consult with CFSAN prior to the submission of an exempt infant formula submission to the extent a manufacturer believes there is such a rationale for a deviation from the provisions of this interim final rule.

(Comment 4) One comment stated that its review of the authorities cited in support of the 1996 proposed requirements calls into question the existence of concrete bases for a number of the proposed "requirements" and thus, appears to reflect "administrative" expertise and thinking as opposed to practical hands-on experience that the industry possesses. Another comment emphasized that the real GMP expertise rests with the infant formula industry, and further argues that reliance by FDA on Agency administrative expertise in response to comments, if unsupported

by additional data, outside expert recommendations, or detailed explanation, may be neither good nor reasonable administrative practice.

(Response) FDA disagrees that real GMP "expertise" rests only with industry and disagrees with the comment's suggestion that the Agency does not have the expertise it needs to establish requirements. Such assertions are unfounded because FDA does have staff with "real GMP expertise" and, in addition, has consulted with experts outside the Agency through the FAC process. Moreover, FDA field and compliance personnel regularly interact with industry staff during inspections and other compliance activities. FDA has also achieved greater insight into the industry's concerns by virtue of the extensive comments submitted by the industry during this lengthy rule-making process. Further, the comment identifies no specific proposed requirement for which it questions the underlying support. Accordingly, FDA is making no changes in response to this comment.

(Comment 5) One comment stated that many of the provisions in the proposed regulation are inflexible and overly prescriptive. The comment requested that FDA establish the results to be achieved in the infant formula manufacturing process, but not prescribe or limit the ways in which the required results can be achieved.

(Response) FDA agrees in part with this comment. To the extent feasible, FDA is establishing requirements for the manufacturing process in a way that describes the result to be achieved and does not specifically mandate how to achieve that result. For example, as noted in this document, § 106.50(d)(3) mandates that the manufacturer establish controls for the removal of air from the finished product, because such controls are necessary to ensure that nutrient deterioration does not occur. The method used and extent of air removal are left to the discretion of the manufacturer. In other cases, the statutory language mandates how to achieve a result, e.g., the vitamins that must be tested at the final product stage for each batch (production aggregate) of infant formula to ensure compliance with required nutrient levels (section 412(b)(3) of the FD&C Act). Specific statutory mandates are reflected in the interim final rule.

(Comment 6) One comment submitted in 2003 states that instead of responding to comments submitted in response to the 1996 proposed rule, the 2003 comment period reopening merely requests comment again without giving any indication of FDA's current views on the rule's major issues. The comment further stated that the 2003 reopening raises new issues not covered in the proposed rule and fails to provide guidance on how FDA proposes to address these issues. The comment argued that the 2003 reopening is at odds with FDA's obligation under the Administrative Procedure Act (APA) to make its views known to the public in a concrete and focused form in order to make criticism or formulation of alternatives possible, and that this format forces industry to comment on a rule that the public does not see until it is in final form. Accordingly, this comment requests that FDA permit an additional round of notice and comment, especially to the extent that FDA intends to draft regulations addressing new substantive issues not in the proposed rule.

(Response) FDA disagrees with the comment's criticism of the 2003 reopening and suggestion that an additional round of notice and comment on the proposed rule is needed. The 2003 reopening provided a 60-day comment period that ended on June 27, 2003. FDA extended the reopened comment period for an additional 60 days to allow interested persons additional time to comment, as requested in a comment. With this extension, the public was provided with a total of 120 days to submit comments during the 2003 reopening.

As noted previously in this document, in 2003, FDA reopened the comment period to receive comments on all issues presented by the 1996 proposed rule. Thus, at the time of the 2003 reopening, the 1996 proposal identified FDA's views on the issues in the rulemaking. This interim final rule only addresses issues that are within the scope of the original proposal. In light of three meetings that occurred between the issuance of the 1996 proposal and the 2003 reopening, FDA also specifically requested in the 2003 reopening comments on a discrete set of issues that were within the scope of the original proposal. These issues were explained clearly, and opportunity to provide comments on these discrete issues, as well as the rule generally, was provided. In 2006, FDA again reopened the comment period on a specific microbiological standard it was considering for *E. sakazakii* (now classified as *Cronobacter* spp.), in addition to other specific issues.

Under the APA, in order to provide adequate notice, a proposed rulemaking, unless a specific exception applies, must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved" (5 U.S.C. 553(b)(3).) In other words, the notice must be sufficient to fairly apprise interested parties of issues involved, but it does not need to specify every precise proposal which the Agency may ultimately adopt as a rule. *Action for Children's Television* v. *FCC*, 564 F.2d 458, 470 (D.C. Cir. 1977). The notice given by FDA in the original 1996 proposal, the 2003 reopening, and later in the 2006 reopening, was sufficient to fairly apprise all interested parties of the issues involved in the rulemaking. Thus, sufficient notice has been given and additional opportunity for comment is not required. Notwithstanding the adequacy of the prior comment periods, we are accepting comments on this interim final rule. For more details on the comment period, see part XVI of this document.

(Comment 7) One 2006 comment objected to the Agency's limiting the additional 2006 comment period to certain issues and expressed concern that the effect of this limitation would be to prevent the submission of information that could have a negative impact on the resolution of important issues. The comment stated that the limited 2006 reopening may result in the promulgation of a GMP regulation that does not reflect current good manufacturing practices and requested that the entire proposed regulation be reopened and that the public be given the opportunity to respond to FDA's reactions to the voluminous comments submitted since 1996.

(Response) FDA disagrees with this comment. First, the 1996 proposal provided sufficient notice of all issues in this interim final rule. Further, the 2003 reopening provided the public with a lengthy opportunity to comment on all issues raised by the 1996 proposal, and this 2006 comment does not specifically address why an opportunity in addition to that provided in 2003 is needed to comment on all issues. Finally, the 2006 reopening provided sufficient notice of the matters at issue in the reopening. In particular, FDA described the significant expert consultations held since the 2003 reopening and provided the Agency's tentative conclusions, including the basis for such conclusions, relying on the information added to the administrative record and comments received on such information from the 2003 reopening. Therefore, ample notice and opportunity for comment has been provided on all aspects of this interim final rule. As noted previously in this document, however, notwithstanding the adequacy of the prior comment periods, we are accepting comments on

this interim final rule (see part XVI of this document).

B. Status and Applicability of the Regulations (Proposed § 106.1)

Proposed § 106.1 described the authority for each subpart of the proposal and the consequences under the FD&C Act of a failure to comply with any of the proposed regulations. FDA is including § 106.1 because it is important for those in the infant formula industry to be aware of the legal consequences of failing to comply with these regulations, which are being issued to implement specific sections of the FD&C Act.

FDA did receive comments supporting § 106.1 as proposed but did not receive any adverse comments. On its own initiative, however, FDA is revising § 106.1 to clarify all of the requirements in subparts F and G of this interim final rule, and also to clarify the legal consequences of failing to comply with certain requirements in subparts F and G of the interim final rule.

Proposed § 106.1(a) stated that subparts B, C, and D prescribe the steps that shall be taken under section 412(b)(2) and (b)(3) of the FD&C Act (i.e., CGMP and quality control procedures requirements, including audit requirements) in processing infant formula, and that the failure to comply with any regulation under these subparts would adulterate the formula under section 412(a)(3) of the FD&C Act. While it is true that subparts B, C, and D describe CGMP and quality control procedures requirements issued under section 412(b)(2) and (b)(3) of the FD&C Act, these are not the only subparts of the interim final rule that contain CGMP and quality control procedures requirements. Subpart F of this interim final rule prescribes records requirements, some of which are part of the requirements for CGMP and quality control procedures issued under the authority of section 412(b)(2) of the FD&C Act. Additionally, some of the CGMP and quality control procedures requirements are codified in subpart G of this interim final rule. Subpart G describes, in part, the content of submissions. Some of the records that make up the content of these submissions are records made as part of requirements for CGMP and quality control procedures issued under the authority of section 412(b)(2).

Because subparts F and G also contain requirements that are properly classified as CGMP and quality control procedures requirements issued under the authority of section 412(b)(2) of the FD&C Act, FDA is revising proposed § 106.1(c) and (d) to include these requirements and the authority under which they are issued. FDA is also revising proposed § 106.1(c) and (d) to explain that the failure to follow these requirements issued under section 412(b)(2) of the FD&C Act will result in an infant formula that is deemed to be adulterated under section 412(a)(3) of the FD&C Act.

Furthermore, FDA is revising proposed § 106.1(c) and (d) to describe requirements in subparts F and G that are issued under the authority of section 412(b)(1) of the FD&C Act, which requires FDA to establish requirements for quality factors. Proposed § 106.1(b) stated that subpart E prescribed the quality factor requirements issued under section 412(b)(1) of the Act. As with CGMP and quality control procedures requirements, however, quality factor requirements are also contained in subparts F and G. Some of the records requirements that are codified in subpart F are records required under the authority to issue quality factor requirements in section 412(b)(1) of the FD&C Act. Likewise, some of the records that make up the content of the submissions required under subpart G of this interim final rule are required under the authority to issue quality factor requirements under section 412(b)(1) of the FD&C Act. Therefore, because subparts F and G contain records requirements that are part of the quality factor requirements, FDA is also revising proposed § 106.1(c) and (d) to explain that the failure to follow any quality factor requirements issued under section 412(b)(1) of the FD&C Act will result in an infant formula that is deemed adulterated under section 412(a)(2) of the FD&C Act.

C. Definitions (Proposed § 106.3)

Section 106.3 of the 1996 proposed rule provided definitions for the following terms: Batch; final-product-stage; indicator nutrient; infant; infant formula; in-process batch; lot; lot number, control number or batch number; major change; manufacturer; microorganism; new infant formula; nutrient; nutrient premix; quality factors; representative sample; shall; and should. In the 1996 proposed rule, each definition in proposed § 106.3 was designated as a subparagraph of the section using letters (for example, the definition of "batch" was proposed § 106.3(a)). Individual designation of definitions in a regulation is no longer standard in Federal regulations. Accordingly, these individual designations have been removed in the interim final rule and are not used in the discussion in this document. Consistent with the 1996 proposed rule, the definitions continue to be listed in alphabetical order.

No comments suggest modification of the definition of proposed § 106.3(q) for "shall" and thus, it is included, as proposed, in § 106.3 of the interim final rule. Because all of the provisions in this interim final rule are mandatory, there is no need for the definition "should" (proposed § 106.3(r)) and accordingly, this definition is deleted in this interim final rule.

The comments FDA received on the definitions of final-product-stage; indicator nutrient; infant; infant formula; nutrient premix; and representative sample supported the proposed definitions. Thus, these definitions are included, as proposed, in the interim final rule.

FDA received comments that suggested revisions to the definitions of the following terms in the proposed rule: Batch; lot; major change; manufacturer; microorganism; new infant formula; nutrient; and quality factors. Based on changes to the proposed definitions of "lot" and "batch," FDA has made conforming changes to the proposed definitions of "in-process batch" and "lot number, control number, or batch number." FDA also received comments that recommended that FDA include additional definitions of the following terms: Minor change; responsible party; specifications; target values; and critical. FDA responds to these comments in this interim final rule.

In addition, FDA is adding a definition for "eligible infant formula" on its own initiative. As discussed in section VIII, FDA is adding provisions to the quality factor requirements in § 106.96 that relate to a formula that could have been or was lawfully distributed in the United States on the 89th day after the publication of this interim final rule. FDA is describing these formulas as "eligible infant formulas," and for clarity, FDA is adding a definition in § 106.3 to describe these formulas.

1. Batch (Proposed § 106.3(a) and Lot (Proposed § 106.3(g))

As described in more detail in this document, FDA believes that during the course of this rulemaking, two related terms, "batch" and "lot," have been used in different ways, potentially causing confusion. These terms describe two volumes of formula that have significance in the production of infant formula. At the same time, FDA has come to understand that the food industry and the drug industry generally do not use these terms in the same way. This is particularly relevant because the

definitions originally proposed were based on FDA's drug manufacturing CGMP regulations in part 210 (21 CFR part 210) and because some formula manufacturers are part of a larger drug manufacturing firm and others are part of a larger food manufacturing firm. Accordingly, in order to achieve necessary clarity, the interim final rule establishes and defines two new terms, "production unit" and "production aggregate," which are substituted for the terms "batch" and "lot" used in the earlier stages of this rulemaking.

The discussion that follows recounts the background and history of the use of the terms "batch" and "lot" in this rulemaking.

In current industry practice, two volumes of formula have significance during the infant formula manufacturing phase: the quantity of formula that can be mixed in the production equipment at one time (the relatively smaller volume) and the amount of formula manufactured during a single production run (the relatively larger volume.) With a continuous production process (which is used by all formula manufacturers), the larger volume is necessarily somewhat co-mingled because there is no cleaning between production of each smaller volume, and in fact, may be purposefully co-mingled through the combination of several smaller volumes to create a single larger volume. Generally speaking, the larger volume is the production volume of particular interest to the formula manufacturer. At certain times, the quantity produced during a single production run may be a much smaller amount. In most cases, the production of two different larger volumes of formula (two different production runs) will be separated by an intervening cleaning of the production equipment. Manufacturers currently sample from the final volume produced from a single production run, which may include co-mingled volumes, for testing both for nutrients and for microbial contamination.

Although section 412 uses the term "batch," the term is not defined. Specifically, section 412(b)(2)(B)(i) of the FD&C Act (21 U.S.C. 350a(b)(2)(B)(i)) requires testing of "each batch of infant formula" for nutrients prior to distribution of the "batch;" section 412(b)(3)(A) of the FD&C Act (21 U.S.C. 350a(b)(3)(A)) requires that "at the final product stage, each batch of infant formula" shall be tested for certain vitamins; and section 412(b)(3)(C) of the FD&C Act (21 U.S.C. 350a(b)(3)(C)) requires that "during the manufacturing process or *at the final product stage* and before distribution," (emphasis added) the formula shall be tested for all nutrients; and section 412(b)(3)(D) (21 U.S.C. 350a(b)(3)(D)) requires that if a nutrient is added to the list in section 412(i) of the FD&C Act (21 U.S.C. (350a(i)), the Secretary shall require that the manufacturer test "each batch." Section 412(b)(2)(E) of the FD&C Act (21 U.S.C. 350a(b)(2)(E)) defines "final product stage" as "the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and not subject to further degradation." The fact that section 412 of the FD&C Act either requires or permits testing of each "batch" of a formula at the "final product stage" illustrates that Congress used the term "batch" to mean the relatively larger, often co-mingled portion of formula in which individually mixed portions of formula are combined.

Unlike "batch," the term "lot" is not used in section 412 of the FD&C Act. The 1996 proposed rule included definitions for "batch" and "lot" (proposed § 106.3(a) and (g), respectively.) These definitions were derived from FDA's drug CGMP regulations in part 210. The proposed rule defined "batch" to mean "a specific quantity of an infant formula or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture." The proposed rule defined "lot" to mean "a batch, or a specifically identified portion of a batch, having uniform character and quality within specified limits; or, in the case of an infant formula produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits."

The proposed rule stated that it was important to maintain consistency throughout FDA's regulations. Therefore, where possible and appropriate, the proposed definitions relied on FDA's regulations in part 210, the CGMP for drugs. Specifically, the definitions in the proposed rule for "batch," "lot," "lot number, control number, or batch number," and "representative sample" were based on the definitions in part 210.

The proposed definitions of "batch" and "lot" contemplated that infant formula would be produced in bulk, that "batch" was considered the relatively larger volume, that "lot" was the relatively smaller volume, and that more than one "lot" could comprise a "batch." The 1996 proposed rule (§ 106.55) used the term "batch" when describing the requirements for evaluating the microbiological quality of powdered formula at the final product stage.

In 2006, following the emergence of *Enterobacter sakazakii* as a contaminant in powdered infant formula, FDA reopened the comment period on the 1996 proposal to receive comments on the microbiological testing scheme. (The organism *E. sakazakii* was reclassified in 2008 to new genus, *Cronobacter* spp. (Ref. 1).) In that reopening, FDA proposed a new microbiological testing scheme for powdered infant formula. The revised testing requirement proposed in the 2006 reopening was confined to testing for *E. sakazakii* and *Salmonella* ssp. This change was based on the findings of the 2006 FAO/WHO Report (Ref. 3) which provided, for the first time, a risk assessment model to describe the factors leading to *E. sakazakii* infection in infants and identified potential risk mitigation strategies. The 2006 FAO/WHO Report also described a microbiological standard sampling plan for *E. sakazakii*, of negative for *E. sakazakii* in 30 × 10 gram samples from each *lot* of powdered infant formula. The microbiological standard for *Salmonella* spp. of negative in 60 × 25 gram samples is well established and was not changed. Details concerning the microbiological testing required for powdered infant formula by this interim final rule are discussed in section V of this document.

In proposing to adopt this microbiological standard, FDA also proposed that the definition of "lot" be modified to be consistent with the statistical basis for the proposed microbiological testing requirements and the agreed upon international terminology. Specifically, FDA stated that the Agency was considering modifying the definition of "lot" to mean "a quantity of product, having uniform character or quality, within specified limits, or, in the case of an infant formula produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits" (71 FR 43392 at 43395).

Unfortunately, the terms "batch" and "lot" were used without adequate distinction in the 2006 FAO/WHO Report and in the 2006 reopening. As noted, the 2006 reopening proposed a revised definition of "lot" (71 FR 43392 at 44395; August 1, 2006.) Under this definition, "lot" would have been the relatively larger quantity of formula, a definition inconsistent with both the

1996 proposal and FDA's drug CGMP definition. Also, at the time of the 2006 reopening, the Agency did not propose a comparable modification of the definition of "batch." As a result of this oversight, the most recently proposed definitions for "lot" and "batch" both refer to the relatively larger quantity of infant formula. Elsewhere in the 2006 reopening notice, the Agency referred to "batch testing" of microorganisms (71 FR 43392 at 43396), a reference intended to identify the relatively larger quantity of formula.

The confusion surrounding "lot" and "batch" is further illustrated by the comments FDA received on the definitions of "batch" and "lot" in response to the 1996 proposal. Specifically, comments reflected that these terms are used inconsistently and that the terms are not used in the same way in formula manufacturing and in drug manufacturing. As a result of the foregoing, FDA believes that there is significant confusion about the meaning of "batch" and "lot," about the relationship between "batch" and "lot," and, most significantly, about the quantity of formula under discussion for the microbial testing requirements of the interim final rule.

FDA has considered the need to resolve this confusion as well as the importance of clarifying the volume of formula associated with the master manufacturing order and the requirements for nutrient and microbiological testing and has concluded that the terms "batch" and "lot" should be replaced in the interim final rule with two new terms, "production aggregate" and "production unit." The interim final rule defines "production aggregate" and "production unit" in a manner that clarifies the volume of formula and stage of production contemplated by each term as well as the relationship between the two volumes of formula. In addition, the definitions of the two terms reflect changes made in response to comments on "batch" and "lot." By incorporating "production unit" and "production aggregate" into the interim final rule, however, FDA does not intend to introduce new concepts or to make significant changes. Rather, the Agency is using new descriptors to clarify the quantity of formula associated with the master manufacturing order and with the requirements for microbiological and nutrient testing.

"Production unit" represents the individually mixed portion of formula and is defined in § 106.3 as "a specific quantity of an infant formula produced during a single cycle of manufacture that has uniform composition, character, and quality, within specified limits." "Production aggregate" is frequently a co-mingled portion of formula composed of one or more production units; it is defined in § 106.3 as "a quantity of product, or, in the case of an infant formula produced by continuous process, a specific identified amount produced in a unit of time, that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a master manufacturing order." Thus, under this interim final rule, as a result of the revision of these definitions and the addition of these new terms:

- "Production aggregate" represents the relatively larger volume of formula and thus, effectively replaces "batch" (the 1996 proposal) and "lot" (the 2006 reopening).
- "Production unit" represents the relatively smaller volume of formula and effectively replaces "lot" (the 1996 proposal). (The 2006 reopening did not specifically propose a term or definition for the relatively smaller volume.)
- A "production aggregate" may consist of one or more "production units." This is consistent with the definition of lot proposed in 1996. ("*Lot* means a batch or a specifically identified portion of a batch. . . .")
- As with "batch" (the 1996 proposal) and "lot" (the 2006 reopening), the term "production aggregate," the term representing the relatively larger volume of formula, incorporates the concept of being produced according to a master manufacturing order.
- The term "production aggregate" (§ 106.3), which refers to the relatively larger volume of formula, is defined both for purposes of conventional manufacturing and continuous process manufacturing. The comparable term from the 1996 proposal did not address the application of the concept to continuous processing.
- As discussed in section V, the requirements for controls to prevent adulteration from microorganisms (§ 106.55) stipulate that testing be conducted on each "production aggregate" of formula. Imposing the testing requirement on the relatively larger volume of formula is consistent with the FAO/WHO report and is also necessitated by the formula industry's use of continuous processing, a production method that generally does not always result in identifiable smaller volumes. Testing the relatively larger volume is consistent with the proposed rule (which would have required each "batch" to be tested), the 2006 reopening (which would have required each "lot" to be tested), and the language in section 412 (which uses the term "batch" to mean the relatively larger, often co-mingled portion of formula in which individually mixed portions of formula are combined.)

In the remainder of this preamble, FDA uses the terms "production unit" and "production aggregate," as appropriate, to minimize confusion and misunderstanding.

(Comment 8) One comment requested that the term "composition" be added to the definition of "batch" in proposed § 106.3, so that the definition would read "uniform composition, character, and quality." The comment stated that the word "composition" adds to the accepted concept of the characteristics of a batch.

(Response) FDA agrees with this comment, and has added the word "composition" to the definition of "production aggregate" in § 106.3. The ordinary meaning of the word "composition" is "a product of mixing or combining various elements or ingredients." (Ref. 6, p.236) A formula with uniform composition will have the various formula components evenly distributed throughout the quantity of formula manufactured; uniform composition directly contributes to the uniform character and quality of a formula, the two other elements in the definition of "production aggregate."

(Comment 9) One comment requested that the Agency strike the term "single" from, and substitute the word "master" in, the proposed definition of "batch." In the proposed definition, "single" modified "manufacturing order." The comment suggested that modifying "manufacturing order" with the word "master" would ensure that in-process adjustments, undertaken so that the batch meets nutritional requirements, would not contravene the definition.

(Response) FDA does not disagree with this comment and thus, has replaced the term "single" with "master" to describe a manufacturing order. "Master manufacturing order" is a term commonly used in the infant formula industry and is used to describe the "recipe" the manufacturer uses to prepare the production aggregate. The Agency understands the comment's underlying concern to be that the proposed definition, which referred to a "single manufacturing order," could be interpreted to mean that a manufacturer is precluded from making in-process adjustments in what this interim final rule refers to as the "production aggregate" as defined in § 106.3. FDA recognizes that a formula manufacturer may be required to make in-process adjustments to ensure that established specifications for the in-process or final product are met. Given the potential

confusion, FDA is making the change requested in this comment.

(Comment 10) One comment stated that the meaning of the phrase "or other material" in the proposed definition of batch was unclear and recommended that it be removed.

(Response) FDA agrees that the phrase "or other material" is not clear. Also, this phrase is not necessary and thus, it is being deleted from the definition of "production aggregate" in § 106.3.

(Comment 11) A comment requested that FDA delete the phrase "within specified limits" from the definition of "batch" asserting that the phrase creates a substantive requirement that could cause confusion. The comment also claimed that manufacturers determine some of the specifications related to the disposition of a batch on a case-by-case basis. The comment further stated that manufacturers have not identified every outer limit for every process and product parameter that would result in rejection and determination of these limits would require an overwhelming amount of technical and administrative resources.

(Response) FDA disagrees that the phrase "within specified limits" creates a substantive requirement for the identification of every outer limit for every process and product parameter that would result in product rejection. The purpose of the "within specified limits" language in this definition is to ensure that the manufactured infant formula is what the manufacturer intends, and reflects both customary practice in the formula industry as well as the requirements in § 106.6(c)(1) to establish specifications. The manufacturer establishes specifications for each production aggregate of formula, which ensures that the manufactured formula meets the nutrient requirements and applicable microbial contamination standards. Thus, the term "within specified limits" ensures that a production aggregate has the uniform composition, character, and quality intended.

As noted, the comment also requested deletion of "within specified limits" because, the comment asserted, specifications are established on a case-by-case basis. FDA disagrees with this justification because manufacturers should not be determining specifications on a case-by-case basis during production of a formula, as the comment seems to suggest. It is crucial that a manufacturer establish appropriate specifications at any point, step, or stage where control is necessary to prevent adulteration prior to manufacturing formula so that the manufacturer can ensure that its process is under control and is able to produce what is intended. Failure to meet predetermined specifications, or failure to perform necessary in-process adjustments to ensure such specifications are met, suggests that the manufacturing process is not adequately controlled to prevent adulteration.

For all of the foregoing reasons, the Agency declines to delete the phrase "within specified limits" and is retaining such phrase in the definition of "production aggregate" in § 106.3.

(Comment 12) FDA received comments on the definition of "lot" (as proposed in 1996) that were similar to comments on the definition of "batch." In particular, these comments suggested removing the phrase "within specified limits" from the definition of "lot," and also recommended that the definition of "lot" include the term "composition." The comments also requested that the definition of "lot" be clarified in terms of production of infant formula by continuous process.

(Response) As explained previously in this document, the concepts of "production aggregate" and "production unit" are closely related and thus, the definitions of these terms should be consistent with one another. Accordingly, FDA agrees that the term "composition" should be added to the definition of "production unit." In addition, in continuous processing manufacture, each production unit needs to have uniform composition, which will help to ensure that the composition of the production aggregate will be uniform and within the specified limits. Accordingly, for the reasons stated in the responses to comment 11, FDA has also added the term "composition" to the definition of "production unit" in § 106.3.

Similarly, for the reasons stated in the response to comment 11, FDA is also retaining the phrase "within specified limits" in the definition of "production unit" in § 106.3.

Finally, the definition of "production aggregate" refers to the production of infant formula by continuous process. FDA recognizes that a single production unit may also be a production aggregate where, for example, only smaller volumes of infant formula are produced.

(Comment 13) One comment stated that the phrase "or other material" is more appropriate in the definition of "lot" than in the definition of "batch" because the definition of "lot" "encompasses raw material lots better than does the definition of batch'."

(Response) FDA disagrees with this comment. The comment is a reflection of the problem resulting from the variety of ways in which the term "lot" is used in manufacturing and also was used in the earlier stages of this rulemaking. The concept of "lots" of raw materials is separate from the concept of "lot," which was used in the 1996 proposed rule, and "production unit," which is the term used in this interim final rule and is defined in § 106.3. The addition of the phrase "or other material" to the definition of production unit is not appropriate because the production unit does not refer to "lots" of raw materials. Therefore, FDA has not added the phrase "or other material" to the definition for "production unit" in § 106.3.

As a result of establishing the new terms "production aggregate" and "production unit" and their definitions, FDA is also making technical revisions to two related definitions that the Agency proposed in 1996. First, FDA is revising proposed § 106.3(f), the definition of "in-process batch" and codifying the new term and definition in § 106.3 of the interim final rule as follows: "*In-process production aggregate* means a combination of ingredients at any point in the manufacturing process before packaging." Similarly, the Agency is revising proposed § 106.3(h), the definition of "lot number, control number, batch number," and codifying the new term and definition in § 106.3 of the interim final rule as follows: "*Production unit number* or *production aggregate number* means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a production aggregate or a production unit of infant formula can be determined."

2. Major Change (Proposed § 106.3(i))

The proposed rule defined "major change in an infant formula" to mean "any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability [2] of

[2] For the purposes of this interim final rule, "bioavailability" (the noun) refers to the degree to which a nutrient is absorbed or otherwise becomes available to the body. Bioavailability may affect the choice of an ingredient; for example, vegetable oil has been substituted for butterfat in infant formulas because the latter is not well absorbed by infants. Bioavailability may also affect the amount of a substance that must be added to a product to ensure adequate delivery of the substance; for example, soy-based formula must contain relatively more calcium than a cow milk formula because the phytate (a phosphorus compound in soy) interferes with the absorption of calcium. "Bioavailable" is an adjectival form of "bioavailability."

nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer." The proposed definition provided seven examples of changes resulting in an infant formula that would be deemed to differ "fundamentally in processing or in composition."

(Comment 14) One comment agreed with the proposed definition of "major change" in proposed § 106.3(i) but suggested revised language for the example in proposed § 106.3(i)(5). The comment suggested that the phrase "containing a new constituent" in proposed § 106.3(i)(5) should be changed to "containing a new nutrient" because, the comment asserted, the purpose of the Infant Formula Act is to ensure proper nutrition and the term "nutrient" is more consistent with that purpose. The comment asserted that the term "constituent" is overbroad, that its use could result in designating as a major change the addition of a wholly innocuous new constituent added at nominal levels, and that such a result is beyond the basic scope of section 412 of the FD&C Act. The comment further argued that this interpretation would require formula manufacturers to submit 90 day notifications for each of these constituents, which would require both the manufacturer and FDA to expend additional resources with no added benefit to the consumer.

(Response) FDA disagrees with this comment and, for two reasons, declines to make the suggested revision to the definition of "major change" in § 106.3 of the interim final rule. First, the use of the term "constituent" is required by the applicable statute. The definition of "major change" in proposed § 106.3(i) was based on the directive in section 412(c)(2) of the FD&C Act, which states that "the term 'major change'" has the meaning given to such term in § 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder." The guidelines referred to in section 412(c)(2) of the FD&C Act are the *Guidelines Concerning Notification and Testing of Infant Formulas* ("the Guidelines") (Ref. 7). The Guidelines list seven examples of changes that cause an infant formula "to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer." Accordingly, in proposed § 106.3(i), FDA listed the seven examples set out in the Guidelines, including, in proposed § 106.3(i)(5), "Any infant formula manufactured containing a new constituent not listed in section 412(i) of the FD&C Act, such as taurine or L-carnitine." Thus, the language in proposed § 106.3(i)(5) was drawn directly from the definitional source identified in the applicable statute.

Second, sound policy reasons support use of the term "constituent" in the definition of "major change" in § 106.3. Constituents other than the nutrients listed in section 412(i) of the FD&C Act ("required nutrients") are added to infant formula (e.g., intentionally added microorganisms), and a new constituent other than a required nutrient could potentially affect the bioavailability of a formula and such nutrients. The Guidelines recognize, and the definition of "major change" incorporates the recognition, that a new constituent other than a required nutrient can potentially affect the bioavailability of nutrients in the formula and the formula as a whole. Thus, from the standpoint of ensuring the bioavailability of the formula matrix as a whole, in addition to the bioavailability of individual required nutrients, use of the term "constituent" in the definition of "major change" is appropriate as a matter of policy. Therefore, FDA is not revising the definition of "major change" in response to this comment.

(Comment 15) Another comment suggested that the conjunction "and" after proposed § 106.3(i)(6) be changed to "or." The comment argued that this revision is appropriate because each of the examples in this section is intended to stand alone and, although more than one example could be applicable in a given situation, all seven are unlikely to occur at the same time.

(Response) The Agency agrees with this comment. Proposed § 106.3(i) includes a list of examples of infant formulas, each of which differs fundamentally in processing or in composition and thus, each is a separate example of a "major change in an infant formula." Accordingly, FDA is revising proposed § 106.3(i) by changing the conjunction "and" to "or" before the last example in the definition of "major change" in § 106.3.

On its own initiative FDA is removing the words "for commercial or charitable distribution" from proposed § 106.3(i)(2). This change is consistent with the definition of "manufacturer" as discussed in this document, in which the Agency declined to include the phrase "for commercial or charitable distribution."

3. Manufacturer (Proposed § 106.3(j))

The proposed rule (§ 106.3(j)) defined "manufacturer" as "a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution."

(Comment 16) One comment suggested that the definition of "manufacturer" be revised so that "manufacturer" means "a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container *for commercial or charitable* distribution (emphasis added)" and asserted that, by including the phrase "commercial or charitable," parents, child care providers, hospitals, and other institutions who prepare formula for infants under their direct care would not be considered a "manufacturer."

(Response) FDA believes that this comment raises an important issue about the breadth of the proposed definition of "manufacturer." The Agency disagrees, however, that including the phrase "commercial or charitable" as a modifier of the word "distribution" would sufficiently clarify that those who prepare infant formula for infants under their direct care are not "manufacturers."

The Agency recognizes that there are several groups of persons who reconstitute powdered or concentrated liquid infant formula or otherwise mix formula and provide that formula to an infant for whom these persons are providing direct care. These persons include parents, daycare providers and other caregivers, and nurses and other healthcare personnel. In addition, in some healthcare settings, there is a designated institutional unit that performs the formula mixing in place of a nurse or other healthcare provider, such as a hospital formula room; these staff mix or reconstitute formula for infants under the direct care of the hospital or healthcare institution. Whether the reconstitution is done by an individual, such as a daycare provider or staff in a hospital formula room, the preparation of the infant formula is an extension of the care-giving function. FDA does not believe that Congress intended that a person who or institution that mixes formula for a child as an extension of the care-giving function be considered a "manufacturer" subject to the requirements established under section 412. Instead, the provisions of section 412 are intended to regulate entities that prepare or reconstitute formula for further distribution because a manufacturing error by one of these entities has greater potential to cause harm by virtue of the broad distribution of its products. Also, the activities of a

hospital formula room or comparable unit are subject to the oversight and standards of the hospital or other institution of which it is a part. Moreover, as a policy matter, FDA does not believe that it is appropriate to interfere with these care-giving relationships by requiring a person who mixes formula for an infant under his/her direct care to adhere to the types of controls the Agency is establishing in this interim final rule.

FDA affirms, however, that a person or institution that reconstitutes formula for subsequent distribution to infants not under the direct care of that person or institution is a "manufacturer" for purposes of the interim final rule. In this situation, the mixing or reconstitution and subsequent distribution are separate activities and are not simply an extension of the care-giving function.

Accordingly, FDA is revising proposed § 106.3(j) to clarify that the term "manufacturer" does not include a person or institution employing such person that prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.

(Comment 17) One comment suggested that a definition for "responsible party" be added to § 106.3 because the proposed definition of "manufacturer" would result in overlapping responsibilities whenever co-packers are involved in the manufacturing of infant formula. This comment suggested defining "responsible party" as "the manufacturer of an infant formula when all manufacturing steps are performed by a single entity; however, when several entities are involved in the manufacture of a given formula, it means the manufacturer or other entity that has agreed to assume responsibility for ensuring that all requirements for notification and assurance under these regulations are satisfied." The comment stated that for certain requirements, the responsible party would replace the manufacturer completely, to avoid duplication and to attribute appropriately actual responsibility for other requirements. The comment asserted that that duplicate responsibilities for the same activity do not serve any purpose in the majority of proposed requirements, and therefore, suggested that the concept of "responsible party" be introduced to eliminate duplication. The comment stated that only for "registration" (*see* proposed § 106.110) would duplicate responsibilities serve FDA's purpose (e.g., for inspections and counterfeit formula surveillance).

(Response) FDA disagrees that a definition for "responsible party" is needed in the interim final rule because, properly understood, the interim final rule will require no duplication of effort.

The Agency believes that the comment did not understand the responsibilities under the proposed rule. These obligations are of two types: The obligation to conduct certain activities according to the requirements of the CGMP regulation and the obligation of certain persons to ensure that there is compliance with the rule's requirements even if such person is not engaged in the specific activities covered by the rule.

In terms of activities, under the interim final rule, any person who satisfies the definition of "manufacturer" in § 106.3 must comply with all the CGMP requirements that cover activities in which such person engages. Thus, if a person conducts all the activities necessary to produce an infant formula in its final packaged form (i.e., prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of a formula, packages the formula, and labels the product for distribution), that person must comply with *all* CGMP requirements established by this interim final rule.

FDA recognizes, however, that in the infant formula industry, a person may contract with another to perform some portion of the formula production process, such as the packaging and labeling phases of manufacture, and there is no legal prohibition to such arrangements. To the extent that a contractor performs any of the activities identified in the definition of manufacturer in § 106.3, the contractor is a "manufacturer" for purposes of those activities under this interim final rule. However, where a person (such as a contractor) performs only a part of the complete infant formula manufacturing operation, that person is obligated to adhere only to the specific parts of the CGMP rule that are relevant to such person's activities. For example, if an entity has contracted to act as a spray dryer for a powdered infant formula, the spray dryer is an infant formula manufacturer under § 106.3 and is responsible for complying with the applicable sections of subpart B (CGMPs), subpart D (Conduct of Audits), and Subpart F (Records and Reports). The specific responsibilities of a given contractor would depend on the terms of the contract. For example, a contactor whose duties under the contract are limited to spray drying infant formula generally would not be responsible for the nutrient testing required under subpart C (Quality Control Procedures), subpart E (Quality Factors), or subpart G (Registration, Submission, and Notification Requirements).

Importantly, in addition to the obligation to comply with the parts of the CGMP rule that apply to the activities of a particular person's operation, the entity who causes the infant formula to be introduced into interstate commerce in its final form for distribution to consumers has an overarching and ultimate responsibility to ensure that all phases of the production of that formula are in compliance with the final CGMP regulations and that the formula is lawful in all respects. Generally, the person who submits the notification required by section 412(c)(1)(B) of the FD&C Act is the person with this ultimate responsibility. (Under section 201(e) of the FD&C Act (21 U.S.C. 321(e)), "person" includes an individual, partnership, corporation, or association.) That is, although a firm can contract out certain parts of formula production, the firm cannot, by the same token, contract out its ultimate responsibility to ensure that the formula that such firm places into commerce (or causes to be placed into commerce) is not adulterated and is otherwise lawful. *See U.S.* v. *Dotterweich,* 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the FD&C Act by anyone who has "a responsible share in the furtherance of the transaction which the statute outlaws"); *United States* v. *Park,* 421 U.S. 658, 672 (1975) (holding that criminal liability under the FD&C Act does not turn on awareness of wrongdoing, and that "agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act" can be held accountable for violations of the FD&C Act). This overarching responsibility flows from the FD&C Act's structure. In particular, the FD&C Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce an adulterated infant formula, 21 U.S.C. 350a(a) and 331(a). Thus, the firm that causes an infant formula to be introduced into interstate commerce is responsible for ensuring that such formula complies with all the requirements under section 412 of the FD&C Act and the interim final rule and thus, is not adulterated, regardless of

who actually carries out the activities covered by the rule.

In terms of an infant formula firm's obligations relating to the use of contractors, FDA notes, as discussed in section X.B, that under § 106.110(b)(4), the manufacturer of a new infant formula must register with FDA and the registration must list all establishments at which the manufacturer intends to manufacture the new formula. FDA advises that the list of establishments required by § 106.110(b)(4) must include the establishments of all contractors involved in the production of the new formula.

4. Microorganisms (Proposed § 106.3(k))

The proposed rule defined "microorganisms" to mean "yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance."

(Comment 18) One comment stated that this definition of "microorganisms" is identical to the definition in the food CGMPs (21 CFR 110.3(i)), which are also applicable to the manufacture of infant formulas. Thus, the comment asserted, the definition of "microorganism" should be deleted as it represents a redundancy.

(Response) The Agency disagrees with this comment. As discussed earlier in this preamble, Congress specifically mandated in section 412(b)(2)(A) of the FD&C Act that the Secretary (and by delegation, FDA) establish regulations for "good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary" to assure that an infant formula provides nutrients in accordance with the FD&C Act and is "manufactured in a manner designed to prevent adulteration of the infant formula." Section 412(a)(3) of the FD&C Act provides that an infant formula is deemed to be adulterated if the "processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary" under section 412(b)(2) of the FD&C Act. FDA is establishing a definition of "microorganisms" in this interim final rule for use with the specific requirements related to such term that have been issued under section 412 of the FD&C Act. Therefore, FDA is not deleting proposed § 106.3(k) in response to this comment, and the definition of "microorganisms" is included in § 106.3.

5. New Infant Formula (Proposed § 106.3(l))

The proposed rule defined "new infant formula" to mean "(1) An infant formula manufactured by a person that has not previously manufactured an infant formula for the U.S. market, and (2) An infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer."

(Comment 19) One comment suggested that the definition of "new infant formula" in proposed § 106.3(l) be changed by replacing the word "means" with the word "includes." The comment stated that this change would make the definition consistent with the FD&C Act and would allow for situations not described in this definition. In addition, the comment suggested removing the phrase "for the U.S. market" from the first part of this definition in proposed § 106.3(l). The comment argued that the phrase "for the U.S. market" does not appear in the FD&C Act's definition of new infant formula. Also, the comment asserted that, for purposes of proposed § 106.110 (New infant formula registration), the phrase would exclude from the definition of "new infant formula" formulas intended for export only.

(Response) FDA disagrees with the comment that the term "means" should be replaced with the term "includes" in the definition of "new infant formula." Although the language in section 412(c)(2) of the FD&C Act allows for situations not described in the definition of "new infant formula," the definition of "new infant formula" in this rule is limited to the situations described in the definition. An infant formula manufacturer must determine whether its formula is a "new infant formula" in order to comply with FD&C Act and its implementing regulations. A precise definition of "new infant formula" will provide these manufacturers with clarity in this area. Therefore, FDA is not revising proposed § 106.3(l) to incorporate this change.

However, FDA is removing the phrase "for the U.S. market," from the first clause of the definition of "new infant formula" as suggested in the comment. As the comment suggests, the definition of "new infant formula" in the proposed rule could be interpreted to exclude formulas for export only from certain requirements under the FD&C Act, e.g. the registration requirements under section 412(c) of the FD&C Act. Therefore, FDA is revising proposed § 106.3(l) to remove the phrase "for the U.S. market" from the first clause of such definition.

In addition, FDA recognizes that a definition of "new infant formula" without the phrase "for the U.S. market" in the first clause of the definition could be interpreted to permit a manufacturer who has been manufacturing and marketing formula abroad to market the same formula that they have been marketing abroad in the United States without registering with FDA under section 412(c) of the FD&C Act or making a submission under section 412(d) of the FD&C Act, provided that the manufacturer made no "major change" to the formula. This is because the formula would not be a "formula manufactured by a person that has not previously manufactured an infant formula" in the proposed definition of "new infant formula." Even without the removal of the phrase "for the U.S. market" from the proposed definition, such definition could be interpreted to permit certain manufacturers who are marketing infant formula abroad to market that formula in the United States without making a submission under section 412(c) of the FD&C Act. For example, a formula could be considered to be excluded from the "new infant formula" definition if made by a manufacturer that has been marketing that formula abroad, but has also previously marketed a different formula in the United States. To avoid any ambiguity and to ensure that an infant formula that is being marketed in the United States for the first time is classified as a "new infant formula," FDA is revising the definition of "new infant formula" (proposed § 106.3(l)) by inserting at the end of the definition "or which has not previously been the subject of a submission under section 412(c) of the FD&C Act for the U.S. market." With the addition of this language, any manufacturer that produces a formula that has not been the subject of such a submission will be considered a "new infant formula," even if that manufacturer has been continuously manufacturing and marketing that formula abroad without making a major change. In addition, as explained in response to comment 328, this change is consistent with the notification requirements for a manufacturer of an infant formula for export only. Although a manufacturer of infant formula for export only must still submit a notification under section 412(c) of the FD&C Act, the formula is not for the U.S. market and the submission requirements in this interim final rule for such a formula differ from those required for an infant formula intended for the U.S. market. Therefore, the addition of the phrase "for the U.S. market" in the second clause of the definition of "new infant formula"

makes it clear that the submission described in section 412(c) of the FD&C Act is that which is submitted for infant formula marketed in domestic commerce.

Although the phrase "or which has not previously been the subject of a submission under section 412(c) of the FD&C Act for the U.S. market" does not appear in the definition of "new infant formula" under the FD&C Act, the inclusion of such a phrase in the definition of "new infant formula" is well within FDA's authority. If the FD&C Act is silent or ambiguous with respect to the meaning of "new infant formula," the Agency may interpret the term based on a reasonable construction of the statute. *See Chevron U.S.A. Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837, 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). There is ambiguity in the definition of "new infant formula" under section 412(c)(2) of the FD&C Act. As noted previously in this document, the word "includes" in the definition of new infant formula in section 412(c)(2) of the FD&C Act indicates that the term "new infant formula" was meant to encompass situations not described in the definition. *See* NORMAN J. SINGER & J.D. SHAMBIE SINGER, 2A SUTHERLAND STATUTORY CONSTRUCTION § 47:7 (7th ed. 2009) (explaining that when a statutory definition declares what it "includes," it "conveys the conclusion that there are other items includable, though not specifically enumerated"). The situations described in the FD&C Act's definition of "new infant formula" do not encompass, for example, a situation where an infant formula manufacturer who has been manufacturing and marketing formula abroad decides to market that formula in the United States.

Because the FD&C Act's definition of "new infant formula" is ambiguous, the Agency may establish a regulation to fill any gaps in that definition so long as it is not "arbitrary, capricious, or manifestly contrary to the statute." *See Chevron,* 467 U.S. at 844. Adding to the definition of "new infant formula" to account for a situation where an infant formula manufacturer who has been manufacturing and marketing formula abroad decides to market that formula in the United States is clearly consistent with the overall purpose of the Infant Formula Act. The Infant Formula Act and the 1986 Amendments were intended to ensure the "safety and nutrition" of infant formulas. *See* Public Law 96–359, 94 Stat. 1190, 1190 (1980). Without defining "new infant formula" as described previously in this document, however, FDA would not be able to ensure the safety and nutrition of all infant formulas imported into the United States, because a firm that had already been manufacturing and marketing a formula abroad would not need to register with FDA or make a submission to FDA demonstrating compliance with the applicable U.S. laws.

6. Nutrient (Proposed § 106.3(m))

The proposed rule defined "nutrient" to mean "any vitamin, mineral, or other substance or ingredient that is required in accordance with the table set out in section 412(i)(1) of the FD&C Act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the National Research Counsel through its development of a Recommended Dietary Allowance or an Estimated Safe and Adequate Daily Dietary Intake range, or that has been identified as essential for infants by the Food and Drug Administration through a **Federal Register** publication."

(Comment 20) One comment suggested limiting the definition of "nutrient" to "any vitamin, mineral, or other substance or ingredient in infant formula that is required by the act or by regulations issued pursuant to the act." The comment asserted that the intent of the proposed definition is to describe the ways in which nutrients can be added to the list of those already required in § 107.100. The comment stated that it interpreted both the proposed language and the suggested revision as applying to "essential" nutrients, and not to other potential or current ingredients in infant formula. On this basis, the comment stated that the regulations should not create restrictions on the ability of a manufacturer to include new ingredients that are in compliance with existing regulations, nor should the regulations affect substances that are being added currently in compliance with existing regulations.

(Response) The proposed definition of "nutrient" included "any vitamin or mineral" or "other substance or ingredient" that is (1) Required in accordance with the table in section 412(i)(1) of the FD&C Act; (2) required by FDA under section 412(i)(2) of the FD&C Act; or (3) identified as "essential" consistent with the regulations in § 107.10(b)(5). FDA believes that the comment confuses the declaration of "required nutrients" and the declaration of "essential nutrients," with the use of "other substances or ingredients" that a manufacturer may add when producing an infant formula that are not declared as either "required" or "essential" nutrients. Thus, the Agency provides the following clarification.

The definition of "nutrient" in proposed § 106.3(m) included not only vitamins and minerals that may be considered required or essential nutrients, but includes the potential for another "substance or ingredient" that is not a vitamin or mineral to be a required or essential nutrient. In the preamble to the 1996 proposal, the Agency stated that "nutrients that are required to be in infant formula under § 107.100 will be referred to as 'required nutrients'"(61 FR 36154 at 36155). Such nutrients include those listed in the table in section 412(i) of the FD&C Act and those that FDA may require, if FDA revises such table by regulation. Importantly, there are currently several vitamins and minerals (i.e., selenium, chromium, and molybdenum) that are considered "essential" nutrients (not "required" nutrients) based on one of the following: (1) Identified as essential by NAS through its development of a recommended dietary allowance or an estimated safe and adequate daily dietary intake range; (2) identified as essential by the FDA through a **Federal Register** publication; or (3) identified as essential under the 10th edition of the Food and Nutrition Board's Recommended Dietary Allowances (RDA), 21 CFR 107.10(b)(5). Under the proposed definition of "nutrient," a vitamin, or mineral, or other substance or ingredient that is "essential" may be declared on the infant formula label when provided at a level considered in the publications as having biological significance, when this level is known (§ 107.10(b)(5)(ii)). Section 107.10(b)(5) limits the label declaration of vitamins and minerals added to in an infant formula that are not otherwise required to those that are "essential." Thus, FDA included, in the proposed definition of "nutrient," those substances "determined to be essential by the Food and Nutrition Board of the National Research Council or by the FDA" to be consistent with § 107.10(b)(5) on labeling information (61 FR 36154 at 36157). In the preamble to the final rule implementing section § 107.10(b)(5), FDA stated that the "declaration of nutrients that are not required by the Infant Formula Act, not considered to be essential by the NAS or FDA, and not at levels considered to have biological significance is considered to be a misbranding violation under section 403(a)(1) of the FD&C Act . . . because including such nutrients in the nutrient table or declaring a nutrient at a level

that may not have biological significance implies a level of significance or usefulness in human nutrition that has not been established" (50 FR 1833 at 1836 (January 14, 1985)). Therefore, under the proposed definition of "nutrient," any vitamin, mineral, and other substance or ingredient that is not a "required nutrient" or an "essential nutrient," as those terms are used in § 107.10, cannot be part of the nutrient declaration of an infant formula. Ingredients that may be considered "nutrients" but that are not "required nutrients" or "essential nutrients" may be added to infant formula provided that the use of the specific chemical form of the ingredient is in accordance with the 'Agency's food additive regulations, is generally recognized as safe (GRAS), or is authorized by a prior sanction. Thus, for these reasons, limiting the definition of "nutrient" to include only substances required under section 412(i) of the FD&C Act, or regulations issued under such section is not warranted. Accordingly, FDA is not changing the definition for "nutrient" in proposed § 106.3(m) in response to this comment.

(Comment 21) One comment questioned FDA's authority to "sub-delegate" to the Food and Nutrition Board of the National Research Council the 'Agency's authority to establish required nutrients and levels for infant formulas.

(Response) The comment asserting that the Agency is "sub-delegating" its responsibility for establishing required nutrients and levels for infant formulas is beyond the scope of this rulemaking because current § 107.10(b)(5) establishes the role of the NAS in designating nutrients essential for infants, and the Food and Nutrition Board is a part of NAS. FDA notes that the NAS Food and Nutrition Board is now part of the IOM and that the Food and Nutrition Board has replaced "Recommended Dietary Allowances" and "Estimated Safe and Adequate Dietary Intake Range" with "Dietary Reference Intakes" (Ref. 8). Thus, the Agency is making technical changes to the definition of "nutrient" in § 106.3 of the interim final rule so that "Institute of Medicine" replaces "National Research Council" and "Dietary Reference Intake (DRI)" replaces "Recommended Dietary Allowance" and "Estimated Safe and Adequate Daily Dietary Intake range."

Because these same out-of-date references are currently used in § 107.10(b)(5), FDA is also making technical revisions to that regulation that identify the role of the Food and Nutrition Board of the IOM for identifying essential nutrients, and that replace "recommended dietary allowance" and "estimated safe and adequate daily dietary intake range" with "Dietary Reference Intake."

(Comment 22) One comment requested that the Agency clarify what is meant by the phrase "has been identified as essential for infants by the Food and Drug Administration through a **Federal Register** publication," and questioned whether nutrients could be identified as essential in **Federal Register** publications that do not constitute rulemaking. The comment recommended broadening the definition to encompass all FDA rulemaking activities related to infant formula and eliminating the last part of the proposed definition (i.e., deleting "through a **Federal Register** publication").

(Response) With respect to whether nutrients may be identified as essential in **Federal Register** publications that do not constitute rulemaking, this comment is beyond the scope of this rulemaking because the process for establishing a nutrient as "essential" is set out in § 107.10(b)(5) of FDA's regulations. FDA advises that the Agency will consider, on a case-by-case basis, the administrative process, including **Federal Register** publication, needed to identify a nutrient as "essential." FDA declines to broaden the definition as requested by the comment.

7. Quality Factors (Proposed § 106.3(o)) and Requirements for Quality Factors (Proposed § 106.96)

In this portion of the preamble, FDA addresses comments regarding the definition of "quality factors" in proposed § 106.3(o). Because the requirements for quality factors identified in proposed § 106.96 are related to the definition of "quality factors" in proposed § 106.3(o), this portion of the preamble also addresses certain comments on proposed § 106.96 that are related to comments received on the definition of quality factors.

The proposed rule defined "quality factors" as "those factors necessary to demonstrate that the infant formula, as prepared for market, provides nutrients in a form that is bioavailable and safe as shown by evidence that demonstrates that the formula supports healthy growth when fed as a sole source of nutrition."

(Comment 23) Several comments expressed confusion about the role of "healthy growth" as a quality factor compared to a quality factor of "normal physical growth." "Normal physical growth" was identified as a quality factor in proposed § 106.96(b).

(Response) In the 1996 proposal, FDA did not intend to establish "healthy growth" as an individual or separate quality factor requirement. Rather, the proposed rule used the broad concept of "healthy growth" to describe what would be achieved when the requirements for all quality factors are met. The Agency noted in the proposed rule (61 FR 36154 at 36179) that "healthy growth" encompasses "all aspects of physical growth and normal maturational development, including maturation of organ systems and achievement of normal functional development of motor, neurocognitive, and immune systems. All of these growth and maturational processes are major determinants of an infant's ability to achieve his/her biological potential, and all can be affected by the nutritional status of an infant." Thus, in the 1996 proposal, FDA recognized that the nutritional status of an infant can affect the growth and developmental process contemplated by the concept of "healthy growth." Currently, well-established reference data derived using non-invasive procedures are not available to characterize body composition of infants, and methods for establishing the requirements for other quality factors discussed in the proposed rule that contribute to "healthy growth" are not available or are impracticable. For this reason, FDA did not propose, and is not establishing in this interim final rule, requirements for quality factors other than normal physical growth and sufficient biological quality of protein. However, as new methodology and appropriate reference criteria become available, FDA will consider amending this regulation by identifying additional quality factors and establishing appropriate requirements to meet the additional quality factors.

(Comment 24) Several comments also expressed confusion about the need for quality factors for individual infant formula nutrients as well as for the formula as a whole.

(Response) As explained in section VIII.A, the 1986 Amendments revised section 412(b)(1) of the FD&C Act by extending the requirements for quality factors to the infant formula as a whole as well to the nutrients required by section 412(i) of the FD&C Act (21 U.S.C. 350a(i)). Thus, by law, FDA must establish requirements for individual nutrient quality factors and the formula as a whole to the extent possible consistent with current scientific knowledge. To alleviate confusion about "healthy growth" and "quality factors," and to clarify that quality factors apply both to the formula matrix and to the

individual required nutrients, FDA has revised the definition of "quality factors." Thus, in the interim final rule, "quality factors" is defined as follows: "*Quality factors* means those factors necessary to demonstrate the bioavailability and safety of the infant formula, as prepared for market and when fed as a sole source of nutrition, including the bioavailability of individual nutrients in the formula, to ensure healthy growth of infants."

In addition to revising the definition of "quality factors," FDA is revising the section of the proposed regulation specifying the minimum quality factors for infant formulas to clarify the relationship between "healthy growth" and "normal physical growth." Proposed § 106.96 addressed the quality factors for infant formula and stated in part: "All infant formulas shall . . . be of sufficient quality to meet the nutritional requirements for healthy growth." The proposed rule appears to have created some confusion about how to comply with such a requirement and how this provision differs from the requirements that infant formula be capable of supporting normal physical growth and be formulated and manufactured with protein that is of sufficient biological quality. A demonstration of "normal physical growth" is a factor that helps to ensure that the infant formula supports "healthy growth." Similarly, a demonstration of sufficient biological quality of the protein is a factor that helps to ensure that the protein in the infant formula (as opposed the entire formula matrix) helps to support healthy growth.

Consistent with the changes to the definition of "quality factors" in § 106.3 of the interim final rule, proposed § 106.96 has been revised by reorganizing § 106.96 to identify the two specific quality factors of normal physical growth and sufficient biological quality of the protein and to set forth the minimum requirements for quality factors for each of the two quality factors. Specifically, § 106.96(a) of the interim final rule identifies the quality factor of normal physical growth and § 106.96(b) of the interim final rule establishes the minimum requirements for that quality factor, and § 106.96(e) of the interim final rule identifies the quality factor of sufficient biological quality of the protein and § 106.96(f) of the interim final rule establishes the requirements for this second quality factor. Consistent with FDA's original intent, § 106.96 of the interim final rule does not identify "healthy growth" as a separate quality factor.

The comments FDA received on the specific quality factor requirements of the proposed rule, FDA's responses to those comments, and the quality factor requirements as established in this interim final rule are addressed in detail in section VIII of this document.

(Comment 25) One comment requested that FDA delete the reference to safety in the definition of "quality factors" in proposed § 106.3(o) to be consistent with the fact that the Infant Formula Act does not deal with "safety" per se, but rather with nutritional adequacy. The comment stated that the omission of a reference to safety is consistent with the fact that the FD&C Act ensures safety in many ways. Consequently, the comment stated, the additional regulation dictated by the Infant Formula Act was only needed to focus on the particular reliance of infants on the nutritional aspects of a food that might substitute for breast milk as their sole source of nutrition.

(Response) FDA disagrees that the Infant Formula Act, and specifically the term "quality factors," does not have aspects related to the safety of an infant formula. While it is true that each ingredient in infant formula must be approved for use as a food additive, be GRAS under the conditions of intended use, or be used in accordance with a prior sanction, it is also true that the ingredients and the combination of ingredients, i.e., the entire infant formula matrix, must be able to support the growth and development of infants. The concept of "bioavailability" is not separate and distinct from the concept of safety. If an infant formula, which is the sole source of nutrition for infants, could not support healthy growth of infants, FDA would not consider the formula to be safe for use by infants. Therefore, FDA disagrees with this comment's request to delete the reference to safety in the definition of quality factors and is not modifying proposed § 106.3(o) in response to the request.

(Comment 26) One comment recommended deletion of "healthy growth" as a quality factor. Another comment requested removal of any reference to "growth" in the definition of quality factors, asserting that the effort to establish "healthy" or "normal" growth as a quality factor is flawed. This comment did not explain the basis for its assertion that "healthy" or "normal" physical growth as a quality factor is flawed.

(Response) As is discussed previously in this document, FDA has revised § 106.96 to clarify that "healthy growth" is not itself a quality factor. Instead, FDA has identified two quality factors, "normal physical growth" and "sufficient biological quality of protein" and has established in § 106.96 of the interim final rule requirements to establish those quality factors. This change has been made to clarify that all quality factors in combination help to ensure that a formula and the individual nutrients in a formula support "healthy growth." "Normal physical growth" is only one factor that helps to ensure healthy growth. As noted previously in this document, as science evolves, FDA will consider whether it is appropriate and feasible to develop additional quality factors that will help to ensure healthy growth and to establish requirements to demonstrate that a formula satisfies those additional quality factors.

FDA disagrees with the comment's claim that the effort to establish "normal physical growth" as a quality factor is flawed. Quality factors pertain to the bioavailability of an infant formula and the individual nutrients in that formula; demonstrating bioavailability helps to ensure that infants will achieve healthy growth when fed the formula as a sole source of nutrition. As discussed previously in this document, and consistent with the 1996 proposal, FDA considers the concept of "healthy growth" to be "broad, encompassing all aspects of physical growth and normal maturational development, including maturation of organ systems and achievement of normal functional development of motor, neurocognitive, and immune systems" (61 FR 36154 at 36179). FDA further recognizes that "all of these growth and maturational development processes are major determinants of an infant's ability to achieve his/her biological potential, and all can be affected by the nutritional status of an infant" (61 FR 36154 at 36179). The report of the House Committee on Interstate and Foreign Commerce (the 1980 Committee Report) that accompanied the Infant Formula Act stated that "growth of infants during the first few months of life is a determining factor for the pattern of development and quality of health in adult life" (Ref. 9). FDA interprets this statement as evidence that the Committee recognized the vulnerable nature of this period of life and the critical role of diet in affecting long-term growth and development during this stage, and that healthy growth involves integration of the myriad processes by which an infant reaches his/her biological growth potential.

The concept of "healthy growth" in the definition of quality factors is not only consistent with the Committee's report, but is also consistent with

discussions of diet and health by several authoritative bodies. For example, the preamble to the Constitution of WHO states that "health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (*http://www.who.int/governance/eb/constitution/en/index.html*) (Ref. 10). While FDA's use of the term "healthy growth" in this regulation does not extend to measures of social well-being, it is otherwise consistent with the concepts in the WHO definition in that normal development is encompassed within the concept of complete physical and mental well-being. The term "healthy growth" is also closely allied with the conceptual framework adopted by the Food and Nutrition Board of the IOM, which established a comprehensive set of reference values for nutrient intakes consistent with the maintenance of good health. For example, in revising the dietary reference intakes for the B vitamins, the IOM considered risk of developmental abnormalities and chronic degenerative disease as well as nutrient functions and their indicators (Ref. 8).

Therefore, FDA is retaining the reference to "healthy growth" in the definition of "quality factors" in § 106.3 of the interim final rule, and is retaining normal physical growth as a quality factor.

(Comment 27) One comment agreed with the critical importance of ensuring the bioavailability of infant formula and stated that growth is clearly an indicator of bioavailability. However, the comment also claimed that it would be inappropriate to establish "healthy growth" or "normal growth" as a quality factor and recommended that neither be included as a quality factor in proposed § 106.96. The comment alleged that there are meaningful scientific weaknesses to establishing growth as a quality factor but did not identify those weaknesses.

The comment also argued that not enough is known about what constitutes optimal growth to make it possible to choose the one perfect standard against which "normal" or "healthy" growth should be judged and that, as a matter of policy, it would be unwise to depend on growth as an outcome. The comment also claimed that focusing on a single outcome may cause FDA problems in being even-handed in its treatment of manufacturers developing new infant formulas although the comment did not explain this assertion.

(Response) FDA agrees that it would be inappropriate to establish "healthy growth" as an individual quality factor but for reasons other than those offered in the comment. As noted previously in this document, all quality factors contribute to demonstrating the bioavailability and safety of a formula and help to ensure "healthy growth." There are many factors that help to ensure "healthy growth," one of them being "normal physical growth" and another being sufficient biological quality of protein. Therefore, because all quality factors help to ensure healthy growth, it would be inappropriate to establish "healthy growth" as a separate and distinct quality factor.

FDA disagrees, however, that it is inappropriate to establish "normal physical growth" as a quality factor. Importantly, FDA does not consider "optimal growth" to be synonymous with "normal physical growth." Demonstrating that a formula supports "normal physical growth" is a scientifically valid means to contribute to demonstrating that the formula (in its entirety) is bioavailable to and safe for the infant. Notably, the IOM committee strongly supported studies of normal physical growth, recommending "that growth studies should continue to be a centerpiece of clinical evaluation of infant formulas and should include precise and reliable measurements of weight and length velocity, and head circumference" (Ref. 4, p. 10).

Even though there may always be debate in the scientific community on what constitutes optimal growth, there is a sufficient knowledge base to establish "normal physical growth" as a quality factor. It is well-established that infants grow steadily and predictably, and there are now data to identify what constitutes "normal physical growth" and how infants *should* grow. Using worldwide data of how infants grow as well as improved statistical procedures, WHO developed new growth standards, which are regarded as the most comprehensive standards for how infants should grow. The Centers for Disease Control and Prevention (CDC) has recommended the use of the WHO growth standards for birth to 2 years of age since 2009 and CDC's determination was formally presented in 2010 (Ref. 11). The 2009 CDC growth charts, based on the WHO Child Growth Standards, are available at *http://www.cdc.gov/growthcharts/who_charts.htm*, and are a valuable clinical tool for both health professionals and clinical investigators. The 2009 CDC growth charts are incorporated by reference in § 106.160(e) of this interim final rule.

(Comment 28) Several comments addressed the use of "healthy growth" as a general quality factor (proposed § 106.96(a)). One comment stated that it would not be possible to achieve a reasonable scientific consensus on what additional functions (in addition to anthropometric measurements of physical growth) might constitute "healthy growth" as it is related to nutrition, suggesting that "healthy growth" should not be a quality factor.

(Response) FDA agrees that "healthy growth" should not itself be a quality factor and accordingly, the Agency is revising both the definition of quality factors in proposed § 106.3(o) and the requirements for quality factors in proposed § 106.97 to clarify this issue. As noted, "healthy growth" is a broad concept, and the definition of "quality factors" in § 106.3 of the interim final rule identifies the achievement of healthy growth as the overall goal of all specific quality factors. Importantly, however, FDA has not established any requirements for demonstrating "healthy growth." As clarified previously in this document, the interim final rule identifies two quality factors ("normal physical growth" and "sufficient biological quality of protein") and establishes requirements that relate specifically to those two quality factors. In particular, § 106.96(b) of the interim final rule establishes the requirements for the quality factor of "normal physical growth," and § 106.96(f) of the interim final rule establishes the requirements for the quality factor of "sufficient biological quality of protein." Meeting the quality factors that are delineated by the Agency, both now and in the future, will help to ensure that the individual nutrients in an infant formula and the infant formula as a whole support healthy growth.

(Comment 29) Several comments favored requiring normal physical growth as a quality factor, and a related comment stated that the only practical way of assessing growth is by physical measurement.

(Response) The Agency agrees with this comment to the extent that the comment asserts that the only practical way of measuring normal physical growth is by physical measurement. Importantly, it is possible that in the future, as science advances, other measures for assessing normal physical growth may be identified, and FDA intends to consider amending the regulations issued in this interim final rule to establish, as appropriate, additional quality factors and associated requirements.

(Comment 30) One comment stated that because of the increasing complexity of formula ingredients, it is more relevant to evaluate the formula's overall nutrient quality and availability than merely assessing selected

individual nutrients required by the FD&C Act.

(Response) To the extent this comment asserts that quality factors should be established for the complete infant formula, FDA agrees.

FDA disagrees with the comment, however, to the extent that it suggests that evaluation of the formula's overall nutritional quality and overall nutrient availability is sufficient or *more* relevant than evaluating the bioavailability of individual nutrients. As explained in this document, it is scientifically appropriate to establish quality factors both for the complete formula and certain individual formula ingredients.

The 1996 proposal noted that individual nutrient bioavailability is especially critical for formula because, for some infants, it serves as the sole source of nutrition at a life stage of particular vulnerability to harm from nutritional insults (61 FR 36154 at 36179). A nutrient is "bioavailable" to an infant if it is "physiologically available in sufficient quantities to perform its metabolic functions;" the factors affecting bioavailability are complex and can be difficult to predict (61 FR 36154 at 36179). Given the documented importance of individual nutrients, it is entirely appropriate that FDA consider identifying quality factors for these nutrients.

Protein is one of the nutrients required to be present in infant formula, and the 1996 proposal discussed in detail the complexity of protein and its central importance in the infant diet (61 FR 36154 at 36181). Therefore, at the present time, protein is the only individual nutrient for which a quality factor should be established, and thus, § 106.96(e) of the interim final rule requires that a formula's protein ingredient be of sufficient biological quality. FDA did not propose, and is not including in this interim final rule, requirements for quality factors for other required nutrients because, for example, methods to determine whether such requirements are met are either not available, or if available, are impractical because they are invasive, technically difficult, or their results cannot be meaningfully interpreted.

A quality factor for the formula's overall nutritional sufficiency (i.e., normal physical growth) and a quality factor for the biological quality of the formula's protein component (i.e., sufficient biological quality) are complementary. Although a growth study can provide an assessment of a formula's overall nutritional sufficiency, such a study has limitations. In particular, an infant may experience normal physical growth in terms of height, weight, and head circumference but nevertheless be malnourished because the protein does not contain all of the essential amino acids at levels and relative proportions needed for healthy growth and development. Said differently, the functional outcome from an ingredient, such as protein, may not necessarily be immediately reflected by anthropometric measures of physical growth. Thus, FDA has concluded that it is scientifically appropriate to establish quality factors both for the overall formula and the individual formula ingredient, protein. See the discussion in section VIII.

Moreover, section 412(b)(1) of the FD&C Act requires FDA to establish, to the extent possible consistent with current scientific knowledge, requirements for quality factors for individual ingredients and the formula as a whole. Thus, § 106.96 of the interim final rule establishes requirements for demonstrating two quality factors: normal physical growth *and* sufficient biological quality of the protein ingredient.

(Comment 31) Several other comments indicated that quality factors requirements for infant formulas should demonstrate not only normal physical growth but also normal development and health of infants during the study period.

(Response) Physical growth and overall development are both aspects of the term "healthy growth." Currently, normal physical growth is a readily available method for evaluating the bioavailability of the infant formula matrix; however, as science evolves, FDA may add additional quality factor requirements that demonstrate that the formula ensures that infants achieve healthy growth. The Agency does not consider it necessary at this time to include in the four-month study period additional quality factors relating to the "health of infants" or "normal development," nor does the comment explain how specifically these additional quality factors would be measured or why four months would be a sufficient period of time within which to expect measurable changes. Thus, the interim final rule does not identify "normal development and health of the infant" as an additional quality factor.

(Comment 32) One comment agreed with the Agency as to the importance of assessing substantive changes in the manufacturing process on nutrient bioavailability, but stated that a broad definition of growth (healthy growth) would not achieve this objective. Another comment requested that FDA put any mention of measurement of "healthy" or "normal growth" into a guidance document to identify when a clinical demonstration of growth is the most appropriate way to demonstrate bioavailability, and that the term "healthy growth" be changed to "expected physical growth" in that guidance. The comment also stated that "expected" is a more meaningful term and refers to the population for whom the formula is intended and can be measured objectively.

(Response) As explained previously in this document, FDA has revised proposed § 106.3(o), the definition of "quality factors," and is not identifying "healthy growth" as an individual quality factor in this interim final rule. Further, FDA does not agree that the term "expected physical growth" should replace the term "healthy growth." Unlike the broad concept of "healthy growth," the term "expected physical growth" is too narrow to describe what a manufacturer must ensure with respect to the bioavailability and safety of the infant formula. The Agency is codifying "normal physical growth" and "sufficient biological quality of the protein ingredient" as the two quality factors in this interim final rule. As science evolves, FDA will consider amending this regulation by identifying additional quality factors.

8. Other Definitions Requested in Comments

(Comment 33) One comment recommended that the Agency adopt a definition of "minor change," and suggested "any new formulation, or any change of ingredients or processes where experience or theory would not predict a possible significant adverse impact on nutrient levels or nutrient availability. Minor changes may or may not affect whether a formula is adulterated under section 412(a) of the FD&C Act; changes that affect whether a formula is adulterated under section 412(a) would require the manufacturer to notify FDA prior to first processing." The comment noted that the 1996 proposal did not mention "minor change," and claimed that the failure to define "minor change" created unnecessary confusion. The comment gave several examples of both minor changes that would require notification prior to first processing, and those that would not require such notification.

(Response) FDA declines to add a definition for the term "minor change" because such a definition is unnecessary. Although the comment asserts that defining "minor change" is needed to dispel confusion, the comment does not explain this statement. The pivotal concept for a

submission required by section 412(d) of the FD&C Act for a new infant formula is whether the change is "major," and, in § 106.3, the interim final rule includes a definition of "major change." This definition of "major change" makes clear that only certain changes are of a type that require the submission under section 412(d) of the FD&C Act; the definition in proposed § 106.3(i) is derived from section 412(c)(2)(B) of the FD&C Act, and, the definition of "major change" in § 106.3 of the interim final rule provides examples of changes that would be considered "major" because they are changes that cause a formula to differ fundamentally in processing or composition. Moreover, elsewhere in this preamble, FDA has affirmed that not every change to a formula is a "major change." Thus, the need for a definition of "minor change" has not been established. Accordingly, FDA is not persuaded to add a definition for "minor change" to this interim final rule.

(Comment 34) A comment suggested adding a definition for the term "critical" in order to limit the scope of "validation" (e.g. § 106.35) to those areas of manufacture that may truly have public health significance. The comment suggested that the term "critical" be defined when describing "systems or equipment that has been designated by the infant formula manufacturer as necessary to control to prevent adulteration." The comment stated that this definition also emphasizes the responsibility of the manufacturer to make a careful determination of which areas of the production process may have public health significance.

(Response) FDA is not persuaded to include a definition of "critical" in the interim final rule. Throughout the interim final rule, the Agency refers to points, steps, stages, equipment, and systems "where control is necessary to prevent adulteration." This is the standard in section 412(b)(2)(A), the relevant statutory provision. Therefore, it is not appropriate to limit or otherwise modify this standard with the term "critical." Accordingly, FDA declines to include a definition of "critical" in the interim final rule.

(Comment 35) One comment suggested defining the term "specifications." The comment stated that FDA should define "specifications" as "quality control limits or standards for raw materials, in-process materials, and finished product, which are established by the manufacturer for purposes of controlling quality and consistency for infant formula. Failure to meet an established specification requires a documented review and material disposition decision." The comment suggests that in the drug industry, there is common acceptance that the term "specification" means a predetermined value or range for a given parameter, which must be met in order to continue the manufacturing process or release the product for distribution. Failure to meet a specification triggers special, non-routine, documented review, not automatic rejection of the product. The comment states that this procedure is appropriate because specifications, like those in infant formula manufacture, are set well within the outer limits that would cause adulteration. In view of this definition, the comment suggests deleting the word "standard" throughout the proposed rule and replacing it with "specifications." If FDA opts to define "specifications" as the outer acceptability limits, the comment strongly recommends that manufacturers be allowed to retain the current tighter control range approach and to determine whether outer acceptability limits need to be established at each given step in the manufacturing process, as opposed to making the establishment of outer limits an absolute requirement in every case.

(Response) FDA agrees that the term "standards" does not add clarity to the interim final rule because any standard would be considered a specification. Thus, the Agency is deleting the term "standards" when used and retaining the term "specifications."

FDA disagrees, however, that the term "specification" needs to be defined in this interim final rule. The term is commonly used and well-understood in the context of CGMP. In proposed § 106.6(c), a manufacturer would have to establish standards or specifications at any point, step, or stage in the production process where control is necessary to prevent adulteration. Controls to ensure quality include planning processes to determine desired product features or characteristics, a system of controls to ensure that the desired product will be consistently produced, and making necessary improvements to the process (Ref. 12). Manufacturers must plan what they intend to produce, institute adequate controls to achieve the desired outcome, and ensure that the controls work so that the desired outcome is consistently achieved. If the outcome is not consistently achieved, one or more corrective actions must be implemented to reach the desired outcome.

This interim final rule embodies the basic concepts of ensuring quality through planning, establishing controls, and providing feedback to ensure necessary improvements are implemented. An infant formula manufacturer must establish controls at all stages of manufacturing to ensure that the finished product, as packaged and labeled, meets the requirements of the FD&C Act. The controls chosen by a manufacturer may include a specific limit (e.g., addition of 60 milligrams (mg) of vitamin C) or a range (e.g., product must be held between 35–45 degrees F). This interim final rule does not require that a manufacturer set specifications at an outer acceptability limit or within a tighter control range, as described by the comment. Instead, the manufacturer has the flexibility to establish those specifications that are necessary to meet the requirements of section 412 of the FD&C Act and not adulterate the product under sections 402(a)(1), (a)(2), (a)(3), or (a)(4) of the FD&C Act.

(Comment 36) One comment suggested defining the term "target value." The comment also suggests defining the term "target value" as "control limits or standards for raw materials, in-process materials, and finished product which are established by the manufacturer for purposes of targeting the manufacturing process to a tight range within broader specifications. Failure to meet an established target value shall result in an immediate review and adjustment, if necessary, during the manufacturing process. No documented review and material disposition is [sic] needed when a target value is not met, provided that the established specifications are met." The comment explained that infant formula manufacturers sometimes establish "target values" within tight specifications so that operators can adjust the process if the target value is exceeded. The comment suggested that the term "target value" should be not defined for purposes of establishing a requirement for them, but, instead, to recognize that some infant formula manufacturers use them for quality control purposes and to distinguish them from specifications because failure to meet a target value should not trigger the kind of detailed and documented review prompted by a failure to meet specifications.

(Response) FDA is not persuaded to define the term "target value" because FDA is not requiring manufacturers to establish target values in this interim final rule. Manufacturers who establish "target values" within their specifications are free to continue this practice. Importantly, however, any target value established by a

manufacturer should be consistent with the manufacturer's specifications. FDA agrees that although a failure to meet a specification shall prompt a detailed and documented review, such review would not be required by the failure to meet a target value that does not also serve as a specification.

V. Subpart B—Current Good Manufacturing Practice

In the 1996 proposed rule, FDA proposed to establish a new subpart B in part 106 of title 21 of the CFR to implement section 412(b)(2) of the FD&C Act. Section 412(b)(2) of the FD&C Act requires the Secretary (and FDA by delegation) to issue regulations to "establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with this subsection and subsection (i) and is manufactured in a manner designed to prevent adulteration of the infant formula." The system proposed by FDA was intended to establish a framework in which manufacturing decisions are left to the formula manufacturer, but also charges a manufacturer with incorporating into its process measures designed to ensure the safety and nutritional quality of the formula. The 2003 reopening requested comments on all aspects of the 1996 proposal, including proposed subpart B. Also, certain provisions of proposed subpart B were the subject of FDA's 2006 request for comments.

FDA received both general comments as well as specific comments on proposed subpart B. These comments are summarized in this document along with the Agency's responses. In addition to the substantive revisions to subpart B noted in this document, FDA is also making minor editorial revisions in this subpart.

A. General Comments

(Comment 37) One comment suggested that the proposed production and in-process control system should be called a Hazard Analysis and Critical Control Point (HACCP) system because it contains the elements of HACCP.

(Response) The Agency disagrees. In this interim final rule, FDA is adopting CGMP requirements for infant formula as mandated by section 412(b)(2) of the FD&C Act. That statutory provision expressly requires that the Secretary establish by regulation good manufacturing practices requirements.

HACCP is a science-based, systematic approach to preventing food safety problems through the identification and the assessment of risk (likelihood of occurrence and severity), and control of the biological, chemical, and physical hazards associated with a particular food production process or practice. Application of HACCP requires the food producer to develop a plan for the manufacturer's particular production process that anticipates food safety hazards and identifies the points (critical control points) in such a process where a failure would likely result in a hazard being created or allowed to persist.

HACCP and CGMP share the common goal of a systematic approach to food safety. CGMP requires that a manufacturer take all necessary steps both to prevent hazards and to ensure that the manufactured product is what was established in the manufacturer's specifications. Although some requirements of this interim final rule may be consistent with a HACCP-based system, this interim final rule establishes CGMP in accordance with section 412(b)(2)(A) of the FD&C Act.

B. Current Good Manufacturing Practices (Proposed § 106.5)

As proposed in 1996, § 106.5(a) stated that the regulations in subpart B defined the minimum current good manufacturing practices for infant formula and that the provisions of part 113 (21 CFR part 113) applied to liquid infant formulas. Under proposed § 106.5(b), the failure to comply with any provision of subpart B, or for a liquid infant formula, any provision of part 113, would cause the formula to be adulterated under section 412(a)(3) of the FD&C Act. The comments FDA received on proposed § 106.5 supported the language without modification.

The Agency has recently become aware of an infant formula product that satisfies the definition of an "acidified food" under § 114.3(b) (21 CFR 114.3(b)). As an acidified food, this infant formula must comply with part 114 (21 CFR part 114). To make § 106.5 a comprehensive statement, FDA is, on its own initiative, revising proposed § 106.5 to clarify that an infant formula that is an acidified food is subject to the requirements of part 114 and that, for an infant formula that is an acidified food, the failure to comply with any provision of part 114 will cause the formula to be adulterated under section 412(a)(3) of the FD&C Act.

C. Production and In-Process Control System (Proposed § 106.6)

In the 1996 proposal, FDA proposed in § 106.6 to require that infant formula manufacturers implement a system of production and in-process controls designed to ensure that all requirements of subpart B are met and that the infant formula is not otherwise adulterated. This system would be required to be set out in a written plan extending to all stages of processing, from receipt and acceptance of raw materials, ingredients, and components, through storage and distribution of finished product. For each point at which control is necessary, a manufacturer would be required to set specifications, monitor the control point, establish a corrective action plan for use when a specification is not met, have an individual qualified by education, training, or experience evaluate the public health significance of any deviation from specifications, and establish recordkeeping procedures.

The Agency received comments on several aspects of § 106.6, which are addressed in this document.

1. Specifications and Failure To Conform to an Established Specification

FDA received comments that addressed "specifications" generally and did not focus on particular requirements of the proposed rule. These comments are relevant to several sections of the proposed rule that require a manufacturer to establish, implement, and enforce specifications. For purposes of clarity and consistency, FDA addresses in this document, in the context of proposed § 106.6, the general comments concerning specifications.

(Comment 38) One comment stated that infant formula manufacturers currently establish very tight internal specifications and that, while the objective during manufacturing is to produce a product that falls within these tight internal specifications, the failure to do so does not necessarily mean that the infant formula product is adulterated. The comment asserted that a deviation that falls outside the tight internal specifications should trigger a formal, documented review and a material disposition decision and should not lead to automatic rejection of the product. The comment explained that a documented review and a material disposition decision is appropriate because specifications are customarily well within the outer limits that would cause adulteration.

(Response) The requirement to establish, monitor, and otherwise apply specifications was included in several places in the proposed rule, including proposed §§ 106.6(c), 106.40(d), 106.40(e), and 106.70. FDA is persuaded by this comment as well as other comments received that it is appropriate to make certain revisions to the proposed rule's specification requirements.

First, FDA is revising proposed § 106.40(d) by removing the proposed requirement that an ingredient, container, or closure that fails to conform to a specification be automatically rejected for use in formula manufacturing and, instead, to provide that such ingredient, container, or closure, as well as any affected infant formula, shall be subject to a formal, documented review and material disposition decision and shall be quarantined pending such review and disposition decision. The disposition decision may be to reject the ingredient, container, or closure or the affected formula; to reprocess or otherwise recondition it; or to approve and release it for use. As stated previously in this document, the CGMP procedures in this interim final rule are designed to prevent the production of an adulterated infant formula. FDA agrees that failure to meet a specification does not necessarily mean that the infant formula manufactured using the ingredient, container, or closure will be adulterated and thus, the ingredient, container, or closure does not need to be automatically rejected. Similarly, in such situations, the affected infant formula need not be automatically rejected. In order for the revision of § 106.40(d) to result in adequate public health protection, however, the manufacturer must have in place a robust procedure to investigate any deviation from its specifications for ingredients, containers, and closures so that the manufacturer can credibly determine whether the deviation from specifications could result in adulteration of infant formula. Such procedure must consist of a documented review of the deviation from a specification, records of such documented review, including the corrective action taken and the disposition of the affected materials, and control of the affected materials pending their appropriate disposition. The failure to follow these procedures would result in the formula being deemed adulterated under section 412(a)(3) of the FD&C Act.

Specifically, under § 106.40(d) of the interim final rule, any deviation from a specification must result in a documented, comprehensive, and systematic examination of the affected ingredient, container, closure, or of the in-process or finished infant formula in which the suspect ingredient, container, or closure was used by an individual qualified by education, training, or experience to perform such examination. An adequate documented review includes: (1) Identification of the specific deviation; (2) a determination of the need for an investigation into the cause of the deviation; (3) evaluation of the material or product that does not conform to the specification to determine whether the deviation has resulted in or may lead to adulteration of infant formula; (4) identification of the action or actions taken to correct, and prevent a recurrence of, the deviation; and (5) documentation of the disposition of the affected material and infant formula products, if any.

Adequate records of the documented review and disposition are critical, and the rule requires a manufacturer to establish and maintain such records. Specifically, under § 106.100(e)(4) of the interim final rule, required records include those showing the identity and conclusions of, and followup by, the qualified individual who investigated a deviation from a master manufacturing order, a failure of a production aggregate or an ingredient of a production aggregate to meet manufacturer's specifications, or a failure to meet any specification applicable to a production process where control is deemed necessary to prevent adulteration.

Accordingly, proposed § 106.40(d) is revised by deleting the requirement to develop written specifications for acceptance or rejection of ingredients, containers, and closures used in manufacturing infant formula. In its place, FDA is establishing a requirement that a manufacturer develop written specifications for ingredients, containers, and closures and develop written procedures to determine whether such specifications are met. The Agency is also establishing a requirement for a documented review and material disposition decision by an individual qualified by education, training, or experience when an ingredient, container, or closure is determined not to meet the manufacturer's specifications.

Comments on other issues pertaining to proposed § 106.40(d) are discussed in section V.H.2.

Adequate public health protection also requires a manufacturer to ensure that any ingredient, container, or closure that does not meet the manufacturer's specifications be controlled under a quarantine system designed to prevent its use in the manufacturer of an infant formula unless and until it is released for such use. Proposed § 106.40(e) would have required that ingredients, containers, or closures be stored in areas clearly designated as "pending release for use," "released for use," or "rejected for use." In addition, proposed § 106.40(e)(3) would have required ingredients, containers, or closures that did not meet a manufacturer's specifications to be rejected and controlled under a quarantine system to prevent their use in the manufacture of infant formula. However, under this interim final rule, a disposition decision based on a failure to meet a specification is not limited to a decision to reject the material; a decision could be made to release the ingredient, container, or closure, or the affected infant formula, for use, or to reprocess or recondition it. The need to control the ingredient, container, or closure, or the affected formula, to prevent its use in the manufacture of infant formula, pending a material review and disposition decision, applies any time a manufacturer fails to meet a specification. Controlling the material under a quarantine system will prevent potentially adulterated material from being used, or from co-mingling it with other material, in the manufacture of an infant formula. Comments discussed elsewhere in this preamble requested clarification with respect to methods that could be used to control and segregate material. Section 106.40(e) describes the ways a manufacturer may quarantine material that has not been released for use due to failure to meet a specification, or that has been rejected for use in the manufacture of an infant formula.

Comments on other issues pertaining to § 106.40(e) are discussed in section V.H.2. Consistent with the changes in § 106.40(d) and (e) of the interim final rule, § 106.40(f) requires a manufacturer to quarantine an ingredient, container, or closure and to conduct a documented review and make a material disposition decision if the ingredient, container, or closure has been, or may have been, exposed to conditions that may adversely affect it.

Comments on other issues pertaining to § 106.40(f) are discussed in section V.H.3.

Similarly, under § 106.50(f) of the interim final rule, failure to meet a specification does not result in automatic rejection. A manufacturer must control, under a quarantine system, in-process material that does not meet specifications pending a material review and disposition decision by a qualified individual. In-process material that does not meet a manufacturer's specifications could potentially adulterate an infant formula, if used. If an affected in-process material is reprocessed or otherwise reconditioned, it must be controlled under a quarantine system, pending a documented review and material disposition decision. Any in-process material that is rejected must also be

controlled under quarantine system to prevent its use in infant formula manufacturing and processing operations.

Finally, at the final production stage, a manufacturer must determine whether the production aggregate may be released for use or distribution. Pending a decision by the manufacturer to release the production aggregate for use or distribution, proposed § 106.70(a) would have required that the manufacturer "hold, or maintain under its control," each production aggregate until the manufacturer determines certain criteria are met. This language was proposed in order to ensure that adulterated formula would not be released (see 61 FR 36154 at 36174). For consistency with changes made to §§ 106.40 and 106.50 related to the need to establish a quarantine system pending a documented review and material disposition decision by a qualified individual, and options to reject, reprocess or otherwise recondition, or approve and release affected material, FDA is making corresponding changes to § 106.70 of the interim final rule.

For purposes of consistency with the changes in §§ 106.40(d), (e), and (f), 106.50(f), and 106.70(a), (b), and (c), FDA is revising § 106.6(c)(4) to state that the review conducted shall be a documented review resulting in a material disposition to reject, reprocess or otherwise recondition, or approve and release the affected article. Likewise, FDA is inserting a new § 106.6(d) that states the requirement to establish a quarantine system pending a documented review and material disposition decision for any article that fails to meet a specification.

These revisions reflect CGMP and are necessary to prevent adulteration of an infant formula, provide consistency across requirements, and clarify, in response to comments, that a failure to meet a specification does not necessarily result in automatic rejection at each stage of the manufacturing process, i.e., for an ingredient, container or closure, for an in-process material, or for a finished infant formula.

FDA also received comments on specific aspects of proposed § 106.6. These comments are discussed in this document.

(Comment 39) One comment regarding specifications focused on proposed § 106.70. This comment expressed support for the intent of this provision, which the comment characterized as preventing the sale and consumption of a formula that is nutritionally or microbiologically inadequate. The comment asserted, however, that the rejection or reprocessing of a batch (production aggregate) of infant formula that falls outside a manufacturer's specifications is an overly prescriptive means of achieving this objective, and explained that a manufacturer assesses deviations from specifications on a case by case basis and that, once reported, all deviations are evaluated by suitably trained personnel who consider the nutritional and public health significance of the deviation. The comment proposed alternative language for proposed § 106.70(b).

(Response) As noted, FDA has revised several provisions of the interim final rule that concern specification deviations, including proposed § 106.70(b). Although FDA declines to adopt the alternative language offered by this comment, the Agency believes that the revisions to proposed § 106.70(b), which clarify the responsibilities of a manufacturer when a production aggregate does not conform to its specifications, respond to the issues raised by the comment.

2. Establishment and Implementation of a Control System (Proposed § 106.6(a))

(Comment 40) One comment suggested that instead of requiring in proposed § 106.6(a) a system to cover all stages of processing, the production and in-process control system should extend to those stages of processing, storage, and distribution that are under the manufacturer's control because, the comment contended, a manufacturer cannot be expected to be responsible for ensuring proper distribution practices. In addition, the comment asserted that, for co-packers, the scope of responsibility of the co-packer is necessarily limited to the specific aspect of manufacturing, storage, or distribution that the co-packer has agreed by contract to handle.

(Response) FDA believes that this comment misunderstands the responsibilities of manufacturers under the interim final rule. As discussed in the response to Comment 17, there are two types of responsibilities under the interim final rule: The obligation to conduct certain activities according to the requirements of the CGMP regulations and the obligation of certain persons to ensure compliance with the rule's requirements even if such person is not engaged in the specific activities covered by the rule. The degree to which a manufacturer must adhere to the interim final rule's CGMP requirements is determined by the specific activities in which such manufacturer is engaged: Under the interim final rule, a manufacturer must comply with all the CGMP requirements that cover activities in which such manufacturer actually engages. Thus, a firm that packages an infant formula is a "manufacturer" as defined in § 106.3 and must comply with all requirements applicable to the operations it performs. For example, a firm that packages an infant formula is responsible for having a production and in-process control plan for that operation. Conversely, the firm that packages the formula is not responsible for production and in-process control requirements that are not related to packaging operations, such as those related to the receipt of raw materials.

For the foregoing reasons, FDA is not persuaded to change § 106.6(a) in response to this comment and, with the exception of minor editorial changes, § 106.6(a) is included in this interim final rule as proposed.

3. Elements of the Production and In-Process Control System (Proposed § 106.6(c))

(Comment 41) Another comment objected to the requirement in proposed § 106.6(c) that the manufacturer take certain actions at any point, step, or stage in the production process where control is necessary to prevent adulteration. The comment argued that "any point, step, or stage" could refer to every conceivable manufacturing activity and there are few manufacturing activities that could not, theoretically, give rise to a finding of "technical" adulteration. The comment stated that it is impractical to fulfill the requirements of proposed § 106.6(c) for every conceivable manufacturing activity and suggested that the regulation be revised to focus on the manufacturing steps most important or critical to ensuring that a product is free from actual adulteration. The comment claimed that this would also make proposed § 106.6(c) consistent with the recordkeeping requirements in proposed § 106.100(e)(3). The comment also emphasized that it is the responsibility of the manufacturer to identify the critical points.

(Response) FDA does not intend that the control procedures established under § 106.6(c) would address every theoretical risk of technical adulteration. Importantly, however, a manufacturer has a responsibility, as part of CGMP, to ensure quality in the finished product on a consistent basis. The way to ensure quality is to identify controls needed at various steps in the production process so that, in its final form, the formula complies with all requirements.

FDA agrees with the comment to the extent that it asserts that certain actions (e.g., the establishing of specifications) are not required at every step in the manufacturer's process. Instead, it is the responsibility of a manufacturer to identify those points at which control is necessary to prevent adulteration of infant formula products. A manufacturer must consider all possible risks likely to occur with its products and determine how these risks will be controlled. These risks include insanitary conditions that may contaminate formula or *may* render a formula injurious to health, not just conditions that do, in fact, contaminate the formula or render it injurious to health. A formula product that has been held under insanitary conditions whereby it may become contaminated with filth or it may be rendered injurious to health is deemed adulterated under section 402(a)(4) of the FD&C Act.

In addition, a manufacturer must determine the controls that are necessary to prevent adulteration during the production of each formula based on the manufacturer's individual operations. Failure to establish specifications under § 106.6(c) at any point, step, or stage where control is necessary to prevent adulteration would cause the product to be adulterated under section 412(a)(3) of the FD&C Act for failure to follow CGMP, including quality control procedures, required by FDA. Accordingly, FDA is not persuaded to make the revisions requested in this comment.

(Comment 42) One comment requested that FDA consider the meaning of the term "specification" in proposed § 106.6(c)(1), which requires that infant formula manufacturers establish standards or specifications to be met at any point, step, or stage in the production process where control is necessary to prevent adulteration.

The comment presented several objections to setting specifications at the outer limits. The comment stated that a manufacturer should be encouraged to impose tight control over its manufacturing process to produce infant formula of consistent quality and noted that infant formula manufacturers set their specifications well within the outer limits that would cause adulteration. The comment noted that, in most cases, manufacturers have not identified every extreme outer limit for every process and product parameter that would result in rejection.

(Response) The Agency believes that this comment misreads the proposed rule. The comment seems to suggest that proposed § 106.6(c)(1) would require a manufacturer to establish a specification at a particular level or range that, if not met, would cause the infant formula to be adulterated. The Agency disagrees with this reading of proposed § 106.6(c)(1). The purpose of § 106.6(c) is to ensure that each manufacturer examines its infant formula production processes and addresses those points, steps, and stages where control is needed to ensure that the process will produce the formula the manufacturer intends to produce. Proposed § 106.6(c)(1) stated that a specification must be established where control is necessary to prevent adulteration but does not specify the range or magnitude of the specification. Also, as discussed in section V.C.1, although proposed § 106.40(d) stated that specifications shall be set for the acceptance or rejection of ingredients, containers, and closures; FDA is revising proposed § 106.40 so that when a formula ingredient, container, or closure fails to conform to specifications, an individual qualified by education, training, or experience must conduct a documented review to determine whether such failure could result in an adulterated infant formula, and thereafter, must make and document a material disposition decision to reject, reprocess or otherwise recondition, or approve and release the material or the affected infant formula for use. Additionally, as discussed in section V.I, FDA is revising § 106.50 so that if any in-process material fails to meet a specification established under § 106.6(c)(1), an individual qualified by education, training, or experience must conduct a documented review and make a material disposition decision to reject, reprocess or otherwise recondition, or approve and release the in-process material. Therefore, a manufacturer may choose to establish a level or range as a specification that must be met in order to produce a formula that is not actually adulterated but is not compelled or encouraged to set its specifications at the outer limits. In fact, a manufacturer may establish a specification within a narrow range to ensure a larger margin of error for some or all of its processes.

In addition, FDA notes that, as discussed in section IV, the Agency is revising, in response to a comment, proposed § 106.6(c)(3) to delete the words "standard or" (see subpart A).

(Comment 43) Several comments suggested changes to proposed § 106.6(c)(3), which would require a manufacturer to establish a corrective action plan to use when a specification, established in accordance with § 106.6 (c)(1), is not met. One comment suggested establishing standard operating procedures (SOPs) for use when a specification is not met as an alternative to a corrective action plan. The comment objected to the language in the preamble to the 1996 proposal that "the best way to ensure that a corrective action is appropriate is to determine the action in advance," asserting that while it may often be feasible to establish corrective action plans in advance, a manufacturer cannot be expected to foresee all future circumstances that may require reliance on a corrective action plan and to predict how it will operate and that many circumstances may have a different set of elements to be considered, thus requiring a case-by-case analysis. The comment stated that a manufacturer could include potential corrective actions in an SOP, but a corrective action should not be mandated when irrelevant to the facts of a given situation.

(Response) FDA is not persuaded to change § 106.6(c)(3) for the following reasons. First, a corrective action plan is one type of SOP that addresses corrective actions. Therefore, a manufacturer may use a SOP as its corrective action plan. Second, although FDA acknowledges that a manufacturer may not foresee all circumstances in which a corrective action will be necessary, such a plan is needed only to respond to the failure to meet a specification. Under § 106.6(c)(1), a manufacturer must set specifications only for those points, steps, or stages in the production process where the manufacturer has determined that control is necessary to prevent adulteration. Thus, the manufacturer should have some familiarity with the circumstances in which a correction action would be required.

Moreover, having in place a corrective action plan for those situations that the manufacturer can anticipate will enable the manufacturer to react more promptly when the anticipated control failure occurs. Even if it is a general mechanism or policy, it is appropriate for a manufacturer to establish a corrective action plan to anticipate the response to a deviation from specifications; the plan should identify what steps should be taken in response to a deviation and by whom. For example, the manufacturer may decide that for certain deviations from a specification, a designated person should stop the production process until a documented review and material disposition decision can be made. In addition, the corrective action plan should include a procedure for the manufacturer's documented review and material disposition decision for the

deviation, but does not need to specify in advance a decision for a set of facts not yet known.

(Comment 44) In response to the 2003 request for comments, one comment stated that corrective actions are based on scientific judgment and past experiences and that if each specification needs to be tested to the point of failure, the cost would be huge and would prevent or severely limit new product development. Given the complex and multi-factorial aspects of infant formula production and the occasional failure of finished products to meet specifications, the comment questioned whether such speculative actions would provide applicable guidance in a specific instance. Instead, if scientific judgment supported by empirical evidence were allowed to determine which specifications should be challenged, some corrective action procedures might be identified in advance, but they would be limited to those situations that manufacturers would reasonably expect to encounter.

(Response) As discussed in response to the previous comment, a corrective action plan is needed only to respond to the failure to meet a specification, and such specifications are not unlimited. That is, under § 106.6(c)(1), a manufacturer is required to set specifications only for those points, steps, or stages in the production process where the manufacturer has determined that control is necessary to prevent adulteration. Thus, FDA does not agree with the comment that the costs of establishing corrective action plans will be overwhelming.

The Agency does agree that a manufacturer cannot predict in advance the outcome of a documented review and material disposition decision for every deviation. However, as the comment recognizes, a manufacturer can anticipate certain corrective actions. For these anticipated deviations, the corrective action plan required under § 106.6(c)(3) will provide a procedure in advance for what, if any, action is needed when a specification is not met, who should take such action, and the process for the documented review and material disposition decision. A manufacturer is expected periodically to revise and include additional relevant information, as appropriate, to a corrective action plan for the identified specifications.

(Comment 45) Several comments were received on proposed § 106.6(c)(4), which requires review of the results of monitoring of production and in-process control points, steps, or stages where control is necessary to prevent adulteration and evaluation of the public health significance of any deviations from established specifications. These comments noted that not all deviations from specifications involve concerns of public health significance; for example, shipper cartons that are found with a printing color that differs slightly when compared to the color standard would not justify a public health significance evaluation. The comments agreed, however, that if a deviation has potential public health significance, a qualified individual must make a documented review and material disposition decision.

(Response) These comments appear to misunderstand the proposed rule. Proposed § 106.6(c)(1) would require a manufacturer to establish specifications only at those points, steps, or stages in the production process where control is necessary to prevent adulteration. The Agency recognizes that a manufacturer may establish specifications that are not related to preventing product adulteration, such as the shade of ink on shipper cartons. Unless the manufacturer determines that a particular specification is necessary to prevent product adulteration, it would not be a specification established under § 106.6(c)(1) and, thus, would not be subject to review under § 106.6(c)(4). For this reason, FDA is not revising § 106.6(c)(4) in response to these comments.

D. Controls To Prevent Adulteration by Workers (Proposed § 106.10)

In the 1996 proposal, FDA proposed in § 106.10 general standards to help ensure that workers involved in the production of infant formula do not cause the formula to become adulterated. The proposed provisions address sufficiency and training of personnel, personal hygiene of production personnel, and safeguarding formula from microbial contamination from production personnel. The Agency received comments on several aspects of proposed § 106.10, which comments are addressed in this document.

(Comment 46) One comment suggested eliminating § 106.10(a) because it is overly prescriptive. The comment stated that the only standard by which one can demonstrate that "sufficient personnel qualified by training and experience, to perform all operations" have been employed by the manufacturer is by demonstrating that an unadulterated infant formula can be routinely manufactured. In addition, the comment argued, because other provisions of the existing and proposed regulations already require that unadulterated products be routinely manufactured, compliance with CGMP requirements should be adequate without the Agency's evaluation of internal staffing matters. The same comment stated that if this section is not deleted, it should be made clear that it is the manufacturer's responsibility to determine what is meant by "sufficient" personnel.

(Response) FDA disagrees with this comment and declines to delete § 106.10(a) from the interim final rule. It is critical that a manufacturer of infant formula employ an adequate number of qualified personnel to staff the manufacturing operation, and the requirement in § 106.10(a) ensures that a manufacturer will provide sufficient trained personnel to achieve compliance with CGMP.

FDA does not believe that § 106.10(a) is overly prescriptive. In fact, the Agency agrees that it is the manufacturer's responsibility to determine what constitutes "sufficient" personnel to perform fully all operations necessary to produce the infant formula in compliance with CGMP. The proposal identified no specific number of workers that must be employed, expressly noting that the Agency "is proposing a general standard for determining how many employees are necessary [but] is leaving the determination of the actual number of employees necessary to the manufacturer's discretion." (61 FR 36154 at 36159). To clarify that the decision regarding sufficiency of personnel is both within the manufacturer's authority as well as an obligation of the manufacturer, FDA is revising proposed § 106.10(a) to emphasize that the "A manufacturer shall employ sufficient personnel," rather than retaining the somewhat ambiguous language of the proposal.

(Comment 47) Another comment stated that it was unrealistic to demand that all individuals be fully trained and experienced in infant formula manufacturing because training must be carried out on the job. The comment suggested that some form of licensing of infant formula manufacturing may be appropriate and suggested that at least one licensed person be present during each shift of infant formula manufacture.

(Response) FDA believes that this comment misinterprets proposed § 106.10(a). FDA proposed that production personnel be qualified by training and experience to ensure that all operations are correctly and fully performed. This provision would simply require an infant formula manufacturer to have, at all times, sufficient numbers of employees in both

supervisory positions and non-supervisory positions who are knowledgeable and qualified to perform the functions necessary to manufacture an infant formula so that the formula is not adulterated. Employees may obtain the necessary knowledge and qualifications through training (which may include formal training and on-the-job training), experience, or a combination of these. FDA recognizes that a new employee may be trained in the manufacture of infant formula on the job, for example, when that new employee is under the supervision of a person trained and experienced in the operation that the new employee is asked to perform. FDA is revising proposed § 106.10(a) to clarify that training may include both education and on-the-job training and to clarify that an employee may be qualified by any combination of education, training, or experience.

Finally, FDA does not currently require any type of licensure for individuals involved in the manufacture of infant formula. The Agency is not aware of any problems that have resulted from of the absence of a licensure requirement and is not aware of the particular benefits that would result from such requirement. The comment did not identify either particular problems or specific benefits related to such licensure. Therefore, FDA is not persuaded to modify § 106.10(a) in response to this comment.

E. Controls To Prevent Adulteration Caused by Facilities (Proposed § 106.20)

In the 1996 proposal, FDA proposed in § 106.20 to require that an infant formula manufacturer implement a system of controls designed to prevent adulteration caused by an infant formula facility. These controls would cover buildings, storage areas, lighting, air filtration systems, appropriate storage of certain chemicals, water quality, plumbing and toilet and hand-washing facilities for employees. FDA received no comments on proposed § 106.20(a), (e), and (g), and those provisions are included in the interim final rule as proposed. The Agency did receive comments on several other aspects of proposed § 106.20, which are addressed in this section.

1. Systems of Separation (Proposed § 106.20(b))

(Comment 48) Several comments on the 1996 proposal objected to proposed §§ 106.20(b) and 106.40(e), which would require an infant formula manufacturer to designate separate areas for holding or storing raw materials (ingredients, containers, and closures), in-process materials, and final infant formula product pending release for use, after rejection for use and before disposition, and after release for use. The comments agreed that each manufacturer must establish an effective system to identify and control materials and finished product before and after release for use, but argued that physical separation of materials was not practical. The comments suggested that we allow separation of materials by a means other than physical separation of materials, including computerized inventory controls and adequately marked pallets. As a result of these comments, in the 2003 reopening, FDA specifically requested additional comment on this issue.

(Response) Based on the comments, FDA is persuaded to revise § 106.20(b) to allow materials to be segregated by means other than physically separate storage areas. It may be desirable to have separate storage areas for holding or storing raw materials, in-process materials, and final infant formula product pending release for use, after rejection for use and before disposition, and after release for use. However, use of physically separate storage areas is not necessary if other systems, such as computerized inventory controls or automated systems of separation, can adequately segregate materials to prevent accidental mixups or co-mingling of materials. A computerized inventory system utilizes technical advances and allows tracking of materials through the use of bar codes and radio frequency identification tags that identify items in a firm's inventory. An inventory system could also employ bar codes to identify and track the material in the production facility; for example, a bar code could identify the material, the item's storage location, when it arrived at its designated storage location, and could be used to reorder the item.

FDA disagrees, however, that marked pallets alone would be adequate to prevent mix-ups of these materials because there is no assurance that specific materials will stay associated with a particular pallet without additional arrangements. For example, unless additional measures are taken to avoid mixups such as physical attachment of the material to the pallet (e.g., materials are shrink-wrapped in plastic to the pallet), there is a risk that the separated materials will accidentally become co-mingled with other materials. The objective of this proposed CGMP requirement is to avoid the mix-up of different materials (or different lots of the same material) and ensure the continuing integrity of such materials through the use of systematic storage methods. Use of shrink-wrapped pallets would be an acceptable storage system so long as the integrity of a pallet's contents is reestablished by rewrapping following penetration of the shrink-wrap.

2. Holding of Rejected Materials (Proposed § 106.20(b)(2))

(Comment 49) One comment objected to proposed § 106.20(b)(2), which would require separation of raw materials, in-process materials, and final product infant formula after rejection for use in infant formula and before disposition. The comment suggested removing the phrase "before disposition" because once a decision is made concerning disposition, the requirement for proper status designation should not end. The comment also suggested that the need for separation of rejected or released finished infant formula also should be acknowledged in proposed § 106.20(b)(2) and (b)(3).

(Response) The Agency agrees that the phrase "before disposition" is not necessary. Any time such materials or formula are rejected, the materials should remain segregated until disposition is completed to avoid co-mingling of rejected and released materials.

FDA also agrees with the comment that the interim final rule should acknowledge that finished infant formula product should be segregated. Therefore, FDA is revising proposed § 106.20(b)(2) to state "After rejection for use in, or as, infant formula." However, FDA is not adding the phrase "or as" to § 106.20(b)(3) of the interim final rule, because the need to segregate released final product is already acknowledged in this provision.

FDA is also making corresponding revisions to § 106.40(e) of the interim final rule.

3. Lighting (Proposed § 106.20(c))

(Comment 50) One comment objected to § 106.20(c) and recommended that this provision be deleted, asserting that it is redundant with food CGMP, § 110.35(b)(5).

(Response) Although this comment refers to § 110.35(b)(5), FDA believes the correct reference to food CGMP is § 110.20(b)(5). The comment did not criticize the substance of proposed § 106.20(c) and did not claim that its more specific requirements were inappropriate for infant formula manufacture. While FDA agrees that the requirements in part 110 (the CGMP for manufacturing, packing and holding human food) apply to infant formula manufacture, redundancy, in and of

itself, is not a reason to eliminate this provision. Indeed, given the nature of infant formula, the manufacturing process is necessarily a more specific and highly sophisticated operation, and all lighting must be adequate for each specific area. Accordingly, § 106.20(c) is included in the interim final rule as proposed.

4. Air Filtration Systems (Proposed § 106.20(d))

(Comment 51) Several comments objected to the requirement of proposed § 106.20(d) that air filtration systems, including prefilters and particulate matter air filters, be used on air supplies to production areas where ingredients or infant formula are directly exposed to the atmosphere and suggested that § 106.20(d) be deleted. One comment stated that proposed § 106.20(d) was overly prescriptive and that CGMP for foods in current § 110.20(b)(6) should be sufficient for infant formula manufacturing facilities. Current § 110.20(b)(6) requires the plant and facilities to "provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces."

(Response) FDA agrees that the requirements in current § 110.20(b)(6) are appropriately applied to infant formula manufacturing facilities. However, the Agency is not persuaded that the requirements of current § 110.20(b)(6) are completely sufficient because current § 110.20(b)(6) does not address air filtration. As stated in the preamble to the 1996 proposal (61 FR 36154 at 36160–36161), proposed § 106.20(d) is designed to improve air quality in formula production areas and thus reduce the potential for contamination by air-borne sources such as spores, molds, and bacteria that may be carried on dust or other air-borne contaminants. The presence of such spores, molds, and bacteria may lead to severe illness, particularly in the vulnerable population consuming infant formula.

Importantly, however, because of differences in plant design, location, and other unique features, the manufacturer can best determine which air filtration system or systems are needed to prevent contamination by air-borne sources in a specific plant. Therefore, FDA is persuaded that the interim final rule does not need to require specific types of filters or prescribe when filters are necessary to prevent air-borne contamination. Accordingly, as revised, the interim final rule requires a manufacturer to identify the parts of the production facility in which there is potential for airborne contamination of ingredients, in-process product, finished product, packing materials, and infant formula contact surfaces, and use air filtration as necessary to prevent contamination of these materials.

(Comment 52) One comment noted that although the Agency referenced the drug CGMP as a formative source for the 1996 proposal, the phrase in the drug CGMP regulations, "when appropriate," was not included in the infant formula CGMP proposed rule. This comment suggested alternative language for the CGMP provision, such as "when there is reason to believe that the air in a particular area of the plant might result in adulteration of the product, measures should be taken to prevent such adulteration, by air filtration or some other means."

(Response) FDA believes that the revision to proposed § 106.20(d), which incorporates the concept of "as appropriate," responds to this comment.

(Comment 53) Another comment stated that proposed § 106.20(d) would require complete air filtration and cooling to be used for all production rooms and maintenance of positive air pressure at all times in these rooms. This comment recommended that air filtration should be required only in areas where there is direct contact between the air and formula, such as in dryers and dehumidifiers.

(Response) FDA believes that this comment misunderstands proposed § 106.20(d). Proposed § 106.20(d) would not have mandated air cooling and positive air pressure in all production rooms; it would have expressly limited prefilters and particulate matter air filters to those production areas where ingredients and infant formula would be directly exposed to the atmosphere. Moreover, as noted, the comments have persuaded FDA to delete the proposed requirement for specific types of filters or when filters are necessary to prevent contamination. Accordingly, § 106.20(d) of the interim final rule requires a manufacturer to identify the parts of the production facility in which there is potential for airborne contamination of ingredients, in-process product, finished product, packing materials, and infant formula contact surfaces and use air filtration as necessary to prevent contamination of these materials.

(Comment 54) In the 2003 reopening, FDA requested comments on types and costs of air filtration systems used by infant formula manufacturers and the costs of making changes to these systems. One comment stated that manufacturers use different filters in different areas of a facility and that prefilters and particulate matter air filters are used on air supplies to production areas and areas where formula may be exposed to the atmosphere. The comment stated that the proposed provision would not result in the expenditure of any additional funds and that a more detailed account of the types and costs of air filtration systems would be wasteful and an undue burden on industry when no public interest would be served by insisting on specific changes in this arena.

(Response) FDA considered the information provided in this comment and, as noted previously in this document in response to Comment 51, the requirement of proposed § 106.20(d) that prefilters and particulate matter filters be used in formula manufacturing facilities is not included in § 106.20(d) of the interim final rule. Thus, the interim final rule will not necessarily result in specific changes to the air filtration systems of infant formula manufacturing facilities.

(Comment 55) Another comment stated that one manufacturer currently has air filtration systems in all areas of the manufacturing plant where infant formula or raw materials may be exposed to the atmosphere. These mechanisms filter all incoming air using pleated filters or bag filters to remove particulate matter. The comment states that FDA should consider the prohibitive cost and level of disruption encountered in changing air filtration systems to meet an increased specification in comparison to systems currently performing to an appropriate standard and posing no risk of contamination of infant formula products.

(Response) FDA believes that the revisions to the interim final rule will avoid the costs and disruptions raised as a concern in this comment. As noted, as revised, § 106.20(d) does not require the use of particular filtration measures (such as prefilters and particulate matter air filters). Instead, the interim final rule requires a manufacturer to employ "appropriate measures" to reach the goal of minimizing the potential for contamination of materials in the manufacturing facility. Such measures may, but are not required to, include the use of air filtration or the location and operation of fans and other air-blowing equipment.

5. Potable Water (Proposed § 106.20(f))

(Comment 56) Several comments objected to the requirement in proposed § 106.20(f)(1) that the fluoride level of the water used in infant formula manufacturing be as low as possible. The comments asserted that this requirement is vague, potentially prohibitively costly, and not needed to address a public health concern. The comments stated that manufacturers strive to produce infant formula products with low fluoride levels utilizing a variety of technologies. One comment suggested that the requirement that fluoride removal equipment be used for fluoridated water would be sufficient. Another comment suggested that the regulation be modified to state that the water used in infant formula manufacturing must "not be fluoridated or shall be defluoridated prior to use." The comment stated that this change more accurately reflects current technology and industry practice.

(Response) In the 1996 proposed rule, the Agency noted that infant formulas are currently manufactured without using fluoridated water and recommended that manufacturers continue their practice of not using fluoridated water in the manufacture of infant formula (61 FR 36154 at 36161). Also as noted in the proposed rule, the NAS recommends a safe and adequate intake of 0.1 to 0.5 mg/day fluoride for infants from 0 to 6 months. Accordingly, the Agency is not persuaded that a requirement that the water used in infant formula manufacturing must "not be fluoridated or shall be defluoridated prior to use" is consistent with the recommendations of the NAS/IOM. The purpose of this requirement is to reduce fluoride levels in water used to produce infant formula and, thereby, reduce the likelihood that fluoride intake of infants consuming finished infant formula product will exceed the tolerable upper intake level of 0.7 mg fluoride/day that has been established by the IOM for infants 0 to 6 months of age (Ref. 8). The glossary of the Environmental Protection Agency (EPA) includes a definition of "defluoridation," which is "The removal of excess fluoride in drinking water to prevent the mottling (brown stains) of teeth" (Ref. 13). Importantly, the EPA definition does not specify an upper fluoride limit for "defluoridated" water. However, the requirement for the fluoride level should better reflect industry practices and, therefore, FDA is clarifying in § 106.20(f) that water used in the manufacture of infant formula shall either be free of fluoride or defluoridated to a level as low as possible. FDA disagrees that requiring a manufacturer to defluoridate water to achieve a level of fluoride "as low as possible" is vague. The Agency is providing some flexibility for the manufacturer to determine the level of fluoride the manufacturer can achieve in its operations to keep such level "as low as possible," should the manufacturer choose to defluoridate water rather than to use water that is not fluoridated.

6. Steam (Proposed § 106.20(h))

(Comment 57) One comment suggested that proposed § 106.20(h) require that only culinary steam in compliance with 3–A Sanitary Standards be used at infant formula product contact points.

(Response) Proposed § 106.20(h) would require that steam in direct contact with infant formula be "safe." FDA has considered this comment and agrees that the interim final rule should require that only culinary steam in compliance with 3–A Sanitary Standards should be used for steam that comes in contact with infant formula product. The interim final rule incorporates by reference at § 106.160 the current 3–A Sanitary Standard for culinary steam, 3–A Sanitary Standards, No. 60903: Method of Producing Steam of Culinary Quality (November 2004) (Ref. 14). The 3–A standard is more specific than the standard of the proposed rule ("safe."). The standard is a method for producing steam of culinary quality that is accepted practice for systems used to process perishable foods and it will ensure that the steam that comes in contact with infant formula will not contaminate the formula. Accordingly, the Agency is revising proposed § 106.20(h) to include the 3–A Sanitary Standard as a requirement for steam that comes into direct contact with infant formula.

7. Employee Toilet Facilities (Proposed § 106.20(i))

(Comment 58) One comment suggested that proposed § 106.20(i) should be deleted because it is redundant with the food CGMP, § 110.37(d) and (e). The comment stated that if proposed § 106.20(i) were retained, it should be revised to include "air dryers" as an alternative to single-service sanitary towels in the toilet facility.

(Response) For the reasons discussed in the response to Comment 1, FDA disagrees with the suggestion to delete proposed § 106.20(i) due to redundancy with the food CGMP regulation, § 110.37(d) and (e). FDA agrees that air dryers are an equally acceptable alternative to single-service sanitary towels in the toilet facility. In the preamble to the 1996 proposal, FDA stated its view that proposed § 106.20(i) would be consistent with the Agency's food CGMP (§ 110.37(d)) and drug CGMP (§ 211.52). Importantly, under both the food CGMP and the drug CGMP, air dryers are permitted as an alternative to single service towels in employee toilet and hand washing facilities. Thus, it is reasonable to include air dryers as an alternative in infant formula manufacturing facilities, and § 106.20(i) has been revised accordingly, along with several minor editorial changes.

F. Controls To Prevent Adulteration Caused by Equipment or Utensils (Proposed § 106.30)

In 1996, FDA proposed in § 106.30 to require that an infant formula manufacturer implement a system of controls designed to prevent adulteration caused by equipment and utensils. The proposed provisions addressed the design, installation, and maintenance of infant formula manufacturing equipment. Specific proposed provisions addressed the accuracy of instruments used in such manufacturing (including their calibration), appropriate time and temperature for storage and processing, and the use of compressed gases in infant formula production operations. The Agency received comments on several aspects of proposed § 106.30, which are addressed in this section. In addition to revisions made in response to comments, FDA has made minor editorial revisions in proposed § 106.30.

1. Design, Cleaning, and Sanitizing of Equipment and Utensils (Proposed § 106.30(b))

(Comment 59) One comment suggested that this section be deleted because it is redundant with FDA's CGMP for food (§ 110.35(d)). The comment further stated that if § 106.30(b) was not removed then a clarification to proposed § 106.30(b) was needed. Section 106.30(b) would require that all surfaces that contact ingredients, in-process materials, or infant formula be cleaned, sanitized, and maintained to protect infant formula from being contaminated by any source. The comment argued that there are some areas where wet cleaning is neither practical nor desirable (e.g., in the infant formula powder manufacturing process) because frequent exposures to moisture should be avoided to reduce the likelihood of microbiological contamination. The comment acknowledged that this proposed

regulation could be interpreted to allow for these unique circumstances, but suggested that a statement, such as "as necessary," be added to this section.

(Response) For the reasons discussed in the response to Comment 1, FDA disagrees with the suggestion to delete proposed § 106.30(b) due to redundancy with the food CGMP regulations, § 110.35(d). Further, FDA did not intend that proposed § 106.30(b) would be interpreted to specify wet cleaning as the most appropriate cleaning method for equipment or utensils used to manufacture infant formula. As the comment notes, proposed § 106.30(b) would permit cleaning and sanitizing of powdered infant formula equipment or utensils by means other than a wet cleaning method. However, FDA does recognize that it may not be necessary to sanitize a contact surface for which wet processing is not used. Therefore, FDA is modifying this provision to require that surfaces be cleaned and sanitized, "as necessary," and be maintained to protect infant formula from being contaminated by any source.

In addition, FDA is deleting the last sentence of proposed § 106.30(b), which states "Sanitizing agents used on food-contact surfaces must comply with § 178.1010." The Food Quality Protection Act of 1996 (Pub. L. 104–170) and the Antimicrobial Regulation Technical Corrections Act of 1998 (Pub. L. 105–324) clarified which sanitizing agents are under the jurisdiction of EPA and which are under the jurisdiction of FDA. For example, a sanitizing agent that is used on a semi-permanent or permanent food contact surface (excluding food packaging) is a "pesticide chemical" subject to the regulatory purview of EPA (section 201(q)(1)(B)(i)(III) of the FD&C Act (21 U.S.C. 321(q)(1)(B)(i)(III)). Most sanitizers used on equipment or utensils to which § 106.30(b) of the interim final rule applies would be sanitizers under EPA's regulatory purview as "pesticide chemicals." To the extent that a sanitizer that a manufacturer uses is a food additive or a GRAS ingredient, such substance is subject to FDA's regulatory purview and such use must comply with applicable FDA laws and regulations. FDA modified proposed § 106.30(b) in view of this change in regulatory authority, in response to the foregoing comments, and with the addition of several editorial changes.

2. Use of Lubricants and Coolants in Infant Formula Manufacture (Proposed § 106.30(c))

(Comment 60) One comment requested that proposed § 106.30(c) be clarified to state that lubricants or coolants that would render the infant formula adulterated if they came in contact with the formula must not come in contact with closures prior to the closing/sealing operation. The comment stated that the requirement is probably implied in proposed § 106.30(c), but requested an explicit statement that the reference to containers and closures means prior to the closing/sealing operation when the hermetic seal is formed. The comment also suggested that the phrase "in a manner not permitted by applicable food additive regulations" be added to the end of this proposed requirement to make it consistent with applicable food additive regulations.

(Response) FDA agrees that lubricants and coolants that would render the infant formula adulterated if they came in contact with the formula must not be allowed to come in contact with containers and closures before the closing/sealing operation. Additionally, such lubricants and coolants must not be allowed to come in contact with containers and closures even after sealing as this may lead to contamination when the container is opened for use. Further, it is not clear that all lubricants that may be used would be necessarily subject to the food additive regulation in 21 CFR 178.3570 for lubricants with incidental food contact. Consequently, FDA is replacing the phrase "if they contaminated the formula" with "if such substances were to come in contact with the formula" in § 106.30(c). In this way, if a particular lubricant is not subject to a food additive regulation, e.g., it is GRAS under certain conditions of use, the requirement would cover all such substances.

3. Controlling Parameters at Points Where Control Is Deemed Necessary To Prevent Adulteration (Proposed § 106.30(d)(1))

(Comment 61) One comment requested that FDA clarify in proposed § 106.30(d)(1) that the infant formula manufacturer is responsible for determining the points where control is deemed necessary to prevent adulteration and the routine intervals necessary for calibration of instruments. The comment did not object to the requirement for the calibration of instruments, but noted that it could prove unduly burdensome if the Agency applied "drug" type compliance standards. The comment stated that including the qualification that infant formula manufacturers bear the final responsibility for determining the frequency and scope of testing would help assure that the standard applied to infant formula is appropriate.

(Response) FDA observes that the comment did not explain what would constitute "unduly burdensome, 'drug' type compliance standards." Moreover, the Agency is not persuaded that the requested clarification is necessary because proposed § 106.30(d)(1) specifically states that instruments and controls shall be calibrated at routine intervals, as specified in writing by the manufacturer of the instrument or control *or as otherwise deemed necessary to ensure the accuracy of the instrument* (emphasis added). Thus, the Agency affirms that proposed § 106.30(d)(1) does provide a formula manufacturer with discretion to determine the calibration frequency for controls and instruments that is required to ensure that these instruments or controls are operating within the correct parameters.

(Comment 62) One comment explained that because of the number of instruments to which this rule will apply, it is possible that certain of the instruments requiring calibration may need to be in use while they are being calibrated. Thus, the comment suggested adding the words "on or before first use" to describe the timing of the initial certification (calibration).

(Response) FDA agrees with this suggestion. Calibrating an instrument against a known reference standard at the time the instrument is first used will be sufficient to ensure the accuracy of testing subsequently done with the instrument to establish that certain specifications are met. Thus, FDA is revising § 106.30(d)(1) in the interim final rule by adding the phrase "at the time of or."

(Comment 63) In response to FDA's 2003 comment period reopening and request for comments on calibration, one comment stated that U.S. formula manufacturers have established calibration and preventative maintenance schedules for appropriate pieces of equipment, that priorities for calibrations and preventative maintenance are linked to "criticality in regard to product quality and safety," and that procedures and schedules are aligned according to the criticality assessments, which vary from company to company, and are often based on the recommendations of the instrument supplier. The comment asserted that the regulation should simply require that calibrations and preventative maintenance be performed on pre-established schedules and according to written procedures as the formula manufacturer determines, based on information from the equipment

supplier where applicable and that a requirement that all instruments need to be calibrated routinely, regardless of function, would result in either the removal of all instruments that the manufacturer deems not critical or the addition of significant new personnel and extensive systems to coordinate and track the calibration program.

(Response) FDA believes that this comments misunderstands the calibration requirement in proposed § 106.30(d)(1) in two important ways. First, only certain instruments and controls used in an infant formula manufacturing operation are subject to calibration under proposed § 106.30(d)(1); that is, not all instruments and controls used in formula manufacturing are required to be calibrated. Specifically, proposed § 106.30(d)(1) requires only those instruments and controls at points where "control is deemed necessary to prevent adulteration" to be accurate and maintained, including by calibration. Second, the proposed rule would require a calibration schedule based on the written specifications of the instrument or control manufacturer or that is otherwise necessary to ensure instrument or control accuracy. Although the comment does not define "criticality," FDA believes that "criticality" and the proposed standard of § 106.30(d)(1) (where "control is deemed necessary to prevent adulteration") are comparable. Thus, the Agency believes that proposed § 106.30(d)(1) is consistent with the comment. Accordingly, FDA is making no revisions in the interim final rule in response to this comment.

(Comment 64) Another comment in response to the 2003 reopening stated that because more specificity is required and that infant formula is the sole source of nutrition for a high risk population, calibration needs to be high and frequent. The comment stated that this frequency is necessitated by the ubiquity of microbes and formula's status as an ideal medium for bacterial growth.

(Response) FDA notes that this comment did not explain the additional "specificity" required, or the relationship between instrument calibration and microbial contamination.

The requirement to calibrate is limited to those instruments and controls used in the manufacture of an infant formula for measuring, regulating, or controlling those parameters where control is deemed necessary to prevent adulteration, such as mixing time and speed, temperature, pressure, moisture, or water activity. To the extent that this comment asserts that calibration should be performed as necessary to prevent microbial contamination that would result in adulteration of an infant formula, FDA agrees with the comment. However, this comment does not require a revision of proposed § 106.30(d)(1). Therefore, in light of the foregoing § 106.30(d) is included in the interim final rule as proposed with minor editorial changes.

4. Areas of Cold Storage (Proposed § 106.30(e)(2))

Several comments questioned the across-the-board storage temperature requirement of 40 °F (4.4 °C) in proposed § 106.30(e)(2).

(Comment 65) One comment argued that instead of requiring that cold storage compartments be maintained at a temperature of 40 °F (4.4 °C) or below, FDA allow manufacturers to establish the appropriate temperature for cold storage compartments that would assure the quality and safety of in-process materials. The comment recommended that the regulations simply state the end point to be achieved, e.g., "cold storage will be maintained at temperatures that prevent growth of harmful microorganisms." The comment acknowledged that in some situations (e.g., the long-term storage of aqueous solutions of nutrients that might support microbial growth), the use of 40 °F as a storage temperature is well-established as appropriate. But, the comment asserted, many materials stored at low temperatures in infant formula plants do not require the use of 40 °F to ensure stability.

(Response) FDA disagrees with this comment. The Agency proposed 40 °F as the maximum temperature for cold storage compartments because a temperature of 40 °F (4.4 °C) is considered to be an appropriate temperature to minimize the growth of pathogens (Ref. 15) and the deterioration of liquid ingredients, nutrients, and the formulated product. The comment did not provide any data, authoritative research, or other material to contradict the information supporting the proposed standard of 40 °F (4.4 °C). Thus, the proposed temperature limit remains appropriate.

(Comment 66) One comment stated that defining cold storage only as 40 °F or lower is incompatible with the manufacture of quality infant formula. Another comment argued that in some cases, the use of temperatures this low may create quality problems for the infant formula, such as mix destabilization and non-homogeneity, which could theoretically result in the final product being adulterated.

(Response) FDA agrees in part with this comment. The Agency is aware that storing some in-process and final formulas at too low a temperature may create quality problems that risk causing a formula to be adulterated. Importantly, however, these problems of precipitation and instability do not exist in all infant formula materials (such as raw ingredients.) Indeed, as noted in Comment 65 there are certain infant formula materials that must be stored at lower temperatures, such as the 40 °F storage temperature originally proposed, in order to maintain quality and safety.

Accordingly, FDA is revising proposed § 106.30(e)(2) to provide infant formula manufacturers with some flexibility in terms of cold storage conditions. Specifically, § 106.30(e)(2) of the interim final rule permits a manufacturer to store in-process material and final formula product (those items that, according to the comments, are susceptible to destabilization or loss of homogeneity) for a limited period of time at a temperature not greater than 45 °F (7.2 °C), provided that the manufacturer has data and other information to demonstrate both that such materials cannot be stored at 40 °F (4.4 °C) without risking an adverse effect on their quality and that the storage conditions (i.e., the time and temperature) used by the manufacturer are sufficient to ensure the safety of the stored product.

It is well-recognized that the microbial load of a substance, the length of time a product is held at a particular temperature, and the nature of the product (e.g., product pH) must be considered when determining safe storage conditions. The maximum temperature of 45 °F (7.2 °C) for cold storage compartments will prevent significant growth of microorganisms of public health significance under certain conditions specific to the product composition and the processing step. (Product composition is a factor in how well a particular formulation will support microbial growth.) For this reason, § 106.30(e)(2)(ii) of the interim final rule requires a manufacturer to have data and other information to demonstrate that the time and temperature conditions are sufficient to ensure product safety. That is, the manufacturer must determine whether a temperature not greater than 45 °F (7.2 °C) will be sufficient for the cold storage of an in-process formula or a final infant formula for the storage period contemplated by the manufacturer. Because the nature of the product will affect the extent of microbial growth, this determination must be product-

specific. FDA will consider the conditions of cold storage (i.e., time and temperature) to be sufficient for a particular product at a particular product stage, provided that there is no significant growth of microorganisms of public health significance during the period of storage. Significant growth is considered to be growth of one or more log colony forming units (CFUs) (Refs. 16 and 17).

(Comment 67) Another comment maintained that the short period of time the materials are held does not justify the use of a 40 °F storage temperature and thus, mandating an absolute maximum temperature of 40 °F for all purposes is not justifiable to protect public health and would require additional capital investments for cooling capacity that would not add value to the product.

(Response) FDA believes that the revision of proposed § 106.30(e)(2) is responsive to this comment. That revision is based in part on the recognition that all infant formula materials do not require identical cold storage conditions and thus, the revision provides a manufacturer with some flexibility in terms of permissible cold storage conditions. In addition, § 106.30(e)(2) of the interim final rule reflects the point made implicitly by the comment that storage time, as well as temperature, is an important factor in ensuring safety of formula materials.

(Comment 68) One comment noted that if it were necessary to ensure that the temperature never rose above 40 °F, the materials would have to be held at even lower temperatures most of the time in order to allow a "margin."

(Response) FDA disagrees with this comment. In addition to specifying a maximum holding temperature and an alternative, proposed § 106.30(e) would require a manufacturer to have in place safeguards to help ensure appropriate storage temperature, including monitoring cold compartment temperatures at appropriate frequencies and equipping such compartments with easily readable, accurate temperature-indicating devices. These provisions are included in § 106.30(e) of the interim final rule. The comment did not explain why these requirements would not be sufficient to ensure that the maximum holding temperature of 40 °F would be achieved without the use of a "margin." Moreover, as discussed previously in this document, FDA recognizes that, in certain circumstances, the 40 °F (4.4 °C) holding temperature could adversely affect product quality. Thus, FDA has revised proposed § 106.30(e)(2) to provide some flexibility in terms of the maximum holding temperature for certain in-process and finished infant formulas.

(Comment 69) Another comment suggested that the maximum temperature of 45 °F (7.2 °C) for cold storage would be appropriate and consistent with § 110.80(b)(3)(i), the Grade "A" Pasteurized Milk Ordinance, industry practice, and equipment design capabilities.

(Response) FDA believes that the revision of proposed § 106.30(e)(2) is responsive to this comment. That revision is based in part on the recognition that all infant formula materials do not require identical cold storage conditions and thus, the revision provides a manufacturer with some flexibility in terms of permissible cold storage conditions. In particular, § 106.30(e)(2) of the interim final rule will permit certain formula materials to be stored at a temperature not greater than 45 °F (7.2 °C) as long as the formula manufacturer has data and other information to demonstrate an adverse effect on the quality of the product if held at 40 °F or below and to demonstrate that there is no significant growth of microorganisms of public health significance during the period of storage.

5. Thermal Processing and Temperature-Recording Devices (Proposed § 106.30(e)(3))

(Comment 70) One comment stated that the thermal processing recording device requirement in proposed § 106.30(e)(3)(ii) is either redundant or in conflict with part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers). The comment observed that proposed § 106.30(e)(3)(ii) requires that a thermal processing temperature-recording device reflect the true temperature, and that § 113.40(e)(2) requires a bias so that the temperature-recording device reads "as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer." The comment stated that part 113 more accurately reflects the needs of a thermal processing system, and suggested that the infant formula CGMP simply refer to the regulations in part 113.

(Response) FDA agrees with these comments and is revising and consolidating certain provisions of proposed § 106.30(e), as discussed in detail in this document.

First, FDA is revising proposed § 106.30(e)(1) to clarify that the requirements in parts 108 and 113 (21 CFR parts 108 and 113) apply to thermally-processed infant formula. This is simply restating an existing requirement. In light of this revision, FDA is deleting the language in proposed § 106.30(e)(3)(ii) that "Thermal processing equipment shall be equipped with temperature-recording devices that will reflect the true temperature on a continuing basis." Thus, § 106.30(e)(1) of the interim final rule states: "Equipment and procedures for thermal processing of infant formula packaged in hermetically sealed containers shall conform to the requirements in 21 CFR parts 108 and 113."

Second, FDA is revising the portion of proposed § 106.30(e)(1) that would require, among other things, that thermal processing equipment used at points where temperature control is necessary to prevent adulteration "be monitored with such frequency as is necessary to ensure that temperature control is maintained," and redesignating it in the interim final rule as § 106.30(e)(5). Under § 108.35(c)(2), thermal processing monitoring frequency would be included in the information required to be submitted in the process filing for the scheduled process. Thus, § 106.30(e)(5) of the interim final rule states that "Such monitoring shall be at such frequency as is required by regulation or is necessary to ensure that temperature control is maintained."

(Comment 71) A comment stated that it was unnecessary to require in proposed § 106.30(e)(3)(ii) that "[c]old storage compartments must be equipped with either temperature-recording devices that will reflect the true temperature, on a continuing basis, within the compartment or, in lieu of a temperature-recording device, a high temperature alarm or a maximum-indicating thermometer that has been verified to function properly" because cold storage temperature monitoring can be acceptably achieved through periodic manual recordings with sufficient frequency to ensure proper temperature control. The comment explained that the large volume liquid mixes in the infant formula manufacturing process do not demonstrate significant temperature changes over time, and therefore, do not warrant the increased capital investment of recording devices and temperature alarms. The comment argued that manual recordings at predetermined intervals are adequate to monitor cold temperature storage conditions.

(Response) FDA agrees that an appropriate method of ensuring that cold storage temperature control is maintained is by manual monitoring compartment temperature on a temperature-indicating device and

recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained. The goal of proposed § 106.30(e)(3)(ii) is to ensure adequate control of cold temperatures. It is feasible to accomplish manually what can also be achieved automatically; in this case, establishing a plan to monitor cold temperatures, monitoring and recording the temperature, and doing so at appropriate intervals, can provide the same assurance as an automatic temperature monitoring system. Accordingly, FDA is adding such manual monitoring to the options originally provided in proposed § 106.30(e)(3)(ii). Thus, an infant formula manufacturer will have four choices for monitoring the temperature of a cold storage compartment: (1) The temperature may be monitored manually using a temperature-indicating device and manually recording the temperature at an appropriate frequency; (2) the compartment may be equipped with a temperature-recording device that will reflect the true temperature, on a continuing basis, within the compartment; (3) the compartment may be equipped with a high temperature alarm that has been verified to function properly and the temperature may be manually recorded at an appropriate frequency; or (4) the compartment may be equipped with a maximum-indicating thermometer that has been verified to function properly and the temperature may be manually recorded at an appropriate frequency.

Additionally, § 106.30(e)(3)(ii) of the interim final rule includes information about making and retaining records. Section 106.30(e)(3)(iii) of the interim final rule takes into account the option to manually monitor temperatures, by stating that "the manufacturer shall, in accordance with § 106.100(f)(3), make and retain records of the temperatures recorded in compliance with § 106.30(e)(3)(ii)." Because § 106.30(e)(3)(iii) of the interim final rule contains the requirement that "the manufacturer shall, in accordance with § 106.100(f)(3), make and retain records of the temperatures recorded in compliance with § 106.30(e)(3)(ii)," FDA is making conforming changes to proposed § 106.100(f)(3). Section 106.100(f)(3) of the interim final rule includes "records in accordance with § 106.30(e)(3)(iii)."

(Comment 72) One comment suggested that proposed § 106.30(e)(4) be deleted because the requirement that thermal process recording devices be biased to not read higher than the calibrated temperature-indicating device is redundant with part 113. Another comment asserted that proposed § 106.30(e)(3)(ii) and proposed § 106.30(e)(4) conflict with one another.

(Response) As noted, FDA is revising proposed § 106.30(e)(1) to clarify that the requirements in parts 108 and 113 apply to thermally-processed infant formula. The requirement of proposed § 106.30(e)(4) is incorporated into § 106.30(e)(1) of the interim final rule by virtue of the reference to the application of the requirements in parts 108 and 113 to thermally-processed formula. Accordingly, in § 106.30(e)(4) of the interim final rule, FDA is deleting the language referring to thermal process recording devices not reading "higher than the calibrated temperature-indicating device for thermal processing equipment."

(Comment 73) A comment argued that the bias in proposed § 106.30(e)(4) relating to cold storage temperature recorders was inappropriate because a slight temperature deviation of the cold storage compartment would have a very small impact on the growth of microorganisms. The comment contended that the proposal appears to equate the importance of a very slight temperature deviation for the sterilization process with a very slight temperature deviation of the cold storage compartment when the two situations are radically different. The comment explained that a one degree Fahrenheit drop in the sterilization temperature could have a significant effect on the process lethality and could result in a failure to meet commercial sterility, whereas a one degree Fahrenheit increase in the temperature of a cold storage compartment would have a very small impact on the growth of microorganisms.

(Response) FDA disagrees with this comment. The purpose of proposed § 106.30(e)(4) is to ensure that a temperature-recording device for a cold storage compartment reflects the actual temperature of the compartment and will not overstate the conditions in the compartment. The accuracy of a temperature-recording device is important given that the record in this rulemaking establishes that a temperature of 40°F (4.4°C) in cold storage compartments will prevent the growth of harmful microorganisms and will prevent spoilage and deterioration of nutrients, all of which could lead to adulteration of the infant formula. Moreover, as noted previously in this document, the impact of temperature variation, including a one degree Fahrenheit increase in temperature, will vary depending upon the initial microbial load of the chilled product, the time the product is held at the elevated temperature, and other product characteristics, such as product hydrogen-ion concentration (pH) (Refs. 16 and 17).

Accordingly, in light of the foregoing comments, § 106.30(e)(4) of the interim final rule provides that "When a manufacturer uses a temperature-recording device for a cold storage compartment, such device shall not read lower than the reference temperature-indicating device."

(Comment 74) One comment objected to the recommendation in the 1996 preamble that "manufacturers should calibrate thermometers for cold storage temperature measurements at least at the beginning and end of each production day . . .." The comment argued that FDA is recommending a calibration frequency that is far more stringent than measurement devices for thermal food processing, which is a process of critical importance. The comment asserted that the frequency for calibration of cold storage temperature measurement devices should be determined by the manufacturer based on the volume, hold time, and location in the manufacturing process.

(Response) FDA agrees with this comment to the extent that the comment asserts that calibration frequency should be determined by the manufacturer based on variables of the manufacturer's process. In addition, in determining the appropriate calibration frequency, a manufacturer should consider the calibration frequency recommended by the manufacturer of the equipment in question.

6. Maintenance of Equipment and Utensils at Regular Intervals (Proposed § 106.30(f))

A number of comments objected to the requirements in proposed § 106.30(f) relating to cleaning, sanitizing, and maintaining equipment and utensils. These comments indicate that there is confusion about what would be required by proposed § 106.30(f).

FDA intended that the requirements of proposed § 106.30(f) would extend to all equipment and utensils used in the production of infant formula, including storage tanks, equipment and utensils used in the ingredient weighing area, in-process and processing equipment and utensils, and container filling, closure, and container packaging equipment. All of the equipment and utensils used in producing infant formula have some potential to cause adulteration of the formula and thus, all must be appropriately cleaned, sanitized, and maintained. Although every piece of equipment and each utensil is not likely

to require the same cleaning, sanitizing, or maintenance, all must be subject to such activities at intervals that will prevent such adulteration.

(Comment 75) One comment questioned whether the requirement of "regular intervals of cleaning, sanitizing, and maintenance" would apply when a production line that ordinarily requires daily cleaning and sanitizing is taken out of service. The comment requested that the Agency clarify that it is the equipment and utensils used in an operating production line for the manufacture of infant formula that must be cleaned, sanitized, and maintained at regular intervals.

(Response) FDA disagrees with this comment. Contrary to the comment's suggestion, these requirements apply equally to the equipment and utensils of an operating production line and to the equipment and utensils of a production line that is taken out of service. FDA recognizes that entire production lines, along with their associated equipment and utensils, may be taken out of service, sometimes for prolonged periods. However, manufacturers must establish cleaning, sanitizing, and maintenance procedures that include a schedule for cleaning and sanitizing, as necessary, and maintaining dormant equipment, including production lines and utensils, prior to reactivating their use.

(Comment 76) Another comment requested that FDA clarify whether the requirement in proposed § 106.30(f) to maintain equipment and utensils and to check and retain records on this maintenance would apply only to major equipment or would include every minor action that is taken to maintain equipment (e.g., changing an "O" ring). The comment argued that if minor actions were included, the requirement would be extensive. The comment also suggested that the terms "maintained" and "maintenance" be deleted from this section.

(Response) As stated previously in this document, because all equipment and utensils used in producing infant formula have the potential to cause adulteration of the formula, all must be appropriately cleaned, sanitized, and maintained. Although every piece of equipment and each utensil is not likely to require the same degree of cleaning, sanitizing, or maintenance, all must be subject to such activities at intervals that will prevent such adulteration. Thus, FDA disagrees with the comment suggesting that the requirement to maintain equipment and utensils, to have a qualified individual check all cleaning, sanitizing, and maintenance, and to make and retain records of such activities should apply only to major equipment.

The requirements of proposed § 106.30(f) include both routine and required maintenance of all equipment as well as any unplanned correction or repair of equipment. Manufacturers generally document the routine servicing of production equipment as part of a preventative maintenance program that identifies the work to be performed and its frequency. Changing an "O" ring, an example given in the comment, may be documented in a preventative maintenance program simply by noting the time, date, and employee involved if changing the "O" ring represents routine, scheduled equipment maintenance. If, however, this activity is an unplanned correction or equipment repair, more detailed documentation would likely be required, including an evaluation of whether the "O" ring failure may have resulted in product adulteration.

The comment did not explain why the words "maintain" and "maintenance" should be deleted from proposed § 106.30(f). Maintaining production equipment and utensils is, like cleaning and sanitizing, an essential part of ensuring that formula does not become adulterated due to equipment and utensils. In fact, changing an "O" ring, an example of "minor" maintenance mentioned in the comment, may be critically important if, for example, the "O" ring is used in pipe connections of the processing system where a defective ring could result in a loss of sterility or allow contaminants to enter the product stream and thus, cause a formula to be adulterated. For these reasons, FDA declines to delete "maintain" and "maintenance" from § 106.30(f) of the interim final rule.

(Comment 77) One comment requested that FDA clarify the meaning of "regular intervals" in the requirement that equipment and utensils used in the manufacture of infant formula be cleaned, sanitized, and maintained "at regular intervals." This comment also requested that FDA clarify that the manufacturer determines the appropriate "regular interval" for cleaning, sanitizing, and maintaining equipment and utensils to prevent adulteration of the infant formula.

(Response) FDA agrees that under proposed § 106.30(f), the manufacturer would determine the intervals between cleaning, sanitation, and maintenance activities that are needed to prevent adulteration of the infant formula. Specifically, a manufacturer is responsible for identifying the "regular interval" for cleaning, sanitizing, and maintaining equipment and utensils that is appropriate to prevent adulteration of the formula. In the preamble to the 1996 proposal, FDA acknowledged that equipment cleaning, sanitizing, and maintenance will vary from plant to plant, concluding that "[e]ach manufacturer should study its own plant and develop a procedure that is tailored to that plant's needs and circumstances." (61 FR 36154 at 36165).

In determining the appropriate interval for these activities, a manufacturer should consider the type and nature of the product being manufactured (e.g., soy-based, milk-based, liquid, powder), the length of production runs, the length of time between equipment and utensil use and their cleaning, and the period of time between cleaning and subsequent use of the equipment and utensils. Because a "regular interval" will generally be plant-specific or operation-specific, FDA declines to specify further the meaning of "regular intervals" in proposed § 106.30(f).

(Comment 78) Another comment objected to the requirement in proposed § 106.30(f) that all cleaning, sanitizing, and maintenance be checked by a qualified individual to ensure that such activities have been satisfactorily completed. The comment asserted that utensils should be cleaned and maintained on an "as needed" basis and that a requirement to check the satisfactory completion would be overly burdensome. Thus, the comment suggested changing proposed § 106.30(f) to only require checking of the cleaning, sanitizing, and maintenance of equipment (not utensils). Another comment suggested that records should be required to document equipment cleaning but not cleaning of utensils.

(Response) FDA disagrees that the requirement that a qualified individual confirm proper cleaning, sanitizing, and maintenance should apply only to equipment and not to production utensils. This requirement is designed to confirm that cleaning, sanitizing, and maintenance have been properly executed. Unless properly cleaned, sanitized, and maintained, utensils, like equipment, can be a source of adulteration. For example, a utensil that is not properly cleaned, sanitized and dried can be a source of microbial contamination.

FDA notes that this review of utensils is not required to be performed immediately after cleaning or sanitizing, as this is left to the manufacturer to address in its procedures. For example, a manufacturer could conclude that, in its operation, it would be sufficient for a qualified individual to check utensils for cleanliness immediately before use.

The Agency agrees that a manufacturer does not need to maintain records of utensil cleaning, sanitizing, and maintenance; proposed § 106.100(f)(4) did not require such records for utensils.

(Comment 79) Another comment proposed that this section be revised to state that only documentation relating to equipment cleaning, sanitizing, and maintenance would need to be reviewed to ensure that those activities have been completed satisfactorily rather than include microbial or other testing required for this verification.

(Response) FDA is not persuaded to revise proposed § 106.30(f) as requested to clarify that a review of records of equipment cleaning, sanitizing, and maintenance alone is sufficient to verify that these activities have been properly completed. Although review of documentation relating to such activities provides some assurance that the activities occurred, such records do not provide evidence that such efforts have been adequately performed. Only physical examination of the equipment and utensils by a qualified individual will provide the necessary level of assurance that cleaning, sanitizing, and maintenance have been satisfactorily completed. This assessment may or may not include the need for microbial or other testing. FDA advises that it is the manufacturer's responsibility to determine the specific means needed to verify that production equipment and utensils have been properly cleaned, sanitized, and maintained in accordance with established procedures.

For all of the foregoing reasons, FDA is not revising proposed § 106.30(f) in response to these comments and is making only minor editorial changes to this requirement.

7. Use of Compressed Gases in the Manufacture of Infant Formula (Proposed § 106.30(g))

(Comment 80) One comment suggested that proposed § 106.30(g) be deleted because it was redundant and is already unlawful under existing regulations to introduce indirect additives or adulterants into infant formulas by way of gases or by any other means.

(Response) For the reasons discussed in section IV.A (response to Comment 1), FDA disagrees with the suggestion to delete proposed § 106.30(g) due to redundancy with other existing regulations. The purpose of this rule is to establish CGMP and quality control requirements designed to prevent the adulteration of infant formula, including controls to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the FD&C Act. In the preamble to the 1996 proposal, the Agency explained that compressed gases may be contaminated with oil, filth, or microbes, and the comment did not dispute that explanation. Accordingly, FDA is not persuaded that this requirement relating to compressed gases is unnecessary, and is making only minor editorial changes in § 106.30(g) of the interim final rule.

G. Controls To Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment (Proposed § 106.35)

In 1996, FDA proposed in § 106.35 to require that an infant formula manufacturer implement a system of controls designed to prevent adulteration due to automatic (mechanical or electronic) equipment. The proposal defined the terms "hardware," "software," "system," and "validation" for purposes of proposed § 106.35, and proposed requirements for the design, installation (including validation), testing, and maintenance of such automatic equipment. The Agency received comments on several aspects of proposed § 106.35, which are addressed in this document.

Several comments suggested that the proposed definition of validation and the validation requirements be stricken from the rule.

(Comment 81) One comment requested that proposed § 106.35 be deleted and recommended that FDA and members of the infant formula industry form a task force to define the scope and content of validation of automated systems used in the production or quality control of infant formula. The comment stated that through such a task force, FDA would be able to assess the cost impact, the degree of industry resources, and time necessary to attain compliance with proposed § 106.35. The comment further recommended that, until this task force has completed these tasks, § 106.35 be removed from part 106.

(Response) FDA is not persuaded to remove proposed § 106.35 from part 106, nor is the Agency persuaded to delay finalizing § 106.35 until a joint FDA-industry task force can discuss the details of systems validation for production and quality control of infant formulas. The comment asserted that the purpose of a joint task force would be to allow FDA to acquire information to assess the cost impact, the degree of industry resources, and time necessary to attain compliance with proposed § 106.35. In FDA's view, the comment periods in this rulemaking serve the same purpose: they have provided an opportunity for interested persons (including the infant formula industry) to submit to FDA relevant information about the provisions of the proposed rule, including details about the effect of the validation provisions of proposed § 106.35. Thus, the infant formula industry had opportunities to submit such information in comments both at the time of the 1996 proposal and in response to the 2003 reopening. In fact, in the notice reopening the comment period in 2003, the Agency expressly requested information on validation practices in the infant formula industry. Accordingly, a joint task force is not necessary and the implementation of § 106.35 need not be delayed. For these reasons, FDA is not removing § 106.35 from the interim final rule in response to this comment.

(Comment 82) Another comment suggested that FDA merely require that processing equipment be "designed, installed, tested, and maintained in a manner that will ensure that it is capable of performing its intended function and of producing or analyzing infant formula."

(Response) Systems validation is critical to ensuring that manufacturing processes for infant formula do not result in the production of adulterated formula and thus, FDA disagrees with this comment. The comment does not dispute that validation of systems and revalidation of modified systems is a basic tenant of CGMP nor does the comment explain why system validation is not necessary either generally or specifically in the case of infant formula manufacture (Ref. 18). In fact, systems validation is broadly recognized as essential to ensuring that a product meeting established specifications can be consistently produced under a manufacturer's system. Thus, FDA declines to adopt the suggestion of this comment.

(Comment 83) One comment asserted that it is unnecessary to rely on validation because the Infant Formula Act requires finished product testing for specific nutrients in each batch of infant formula.

(Response) FDA believes that this comment confuses system validation and system verification. System validation is the process by which a manufacturer ensures that a system, if operating properly, is capable of producing, on a consistent basis, a product (e.g., an infant formula) that meets the manufacturer's specifications. In contrast, verification is an on-going determination that the validated system is performing as necessary to produce a product that conforms to specifications. Nutrient testing is a form of verification of a system's proper operation. To the

extent that such testing shows that a particular production aggregate of infant formula does not meet specifications, the operation of the manufacturing system is not verified and the validation of the system is called into question. Given this distinction between validation and verification, FDA disagrees that finished product testing for nutrients eliminates the need for system validation.

(Comment 84) One comment claimed that FDA has proposed an all-encompassing definition of "validation" that is well beyond the scope applied even in the drug industry. The comment explained that drug validation must be precise because it is imperative that drugs contain the precise amount of active ingredient to achieve efficacy in treating illness. Because the margin of safety for drugs can be so critical, their manufacture requires far more critical tolerances than do infant formulas. The comment stated that requiring strict "drug-like" validation and revalidation of systems for infant formula would be extremely costly, unnecessarily burdensome, and a disincentive for process improvements.

(Response) FDA disagrees that the proposed definition of "validation" is overly broad. In the 1996 preamble (61 FR 36154 at 36166), FDA explained the basis of the definition of "validation" in proposed § 106.35(a)(4) as follows: The proposed definition is derived from the ISO International Guideline ISO–9000–3, (which defines "validation" as "the process of evaluating software to ensure compliance with specified requirements"); the IEEE Standard 610.12–1990, which (defines it as "the process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements'"); and FDA's "Glossary of Computerized System and Software Development Terminology," which defines it as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics" (Ref. 19).

All three sources of the proposed definition have in common the concept that "validation" involves the evaluation of a system or a system component to ensure that it meets established specifications or requirements. The ISO definition was revised shortly after FDA issued the 1996 proposal. The current ISO definition of validation (ISO 8402:1994) is "a step beyond verification to ensure the user needs and intended uses can be fulfilled on a consistent basis." The other two sources of the proposed definition of validation, IEEE Standard 610.12–1990 (Ref. 19) and FDA's "Glossary of Computerized System and Software Development Terminology" (Ref. 20), are unchanged.

The proposed definition of "validation" is largely derived from FDA's guidance, "Glossary of Computerized System and Software Development Terminology." This document is intended to serve as a glossary applicable to software development and computerized systems in all FDA regulated industries. As such, the guidance document's definition of "validation" applies equally to all product areas regulated by FDA, including human drugs. Thus, FDA disagrees with the comment's claim that the proposed definition of "validation" is "well beyond the scope applied even in the drug industry."

Moreover, the comment does not dispute the importance of systems validation. As noted, validation of systems and revalidation of modified systems is a basic principle of CGMP, one that is essential to ensuring that a consistent product can be produced under the manufacturer's system. Like drug manufacturing systems, the system used to produce infant formula must be able to produce a product that meets the manufacturer's specifications and all applicable regulatory requirements.

Finally, although the comment claims that validating all systems used to manufacture infant formula before first use would be extremely costly, unnecessarily burdensome, and create a disincentive for process improvements, the comment does not explain the basis of these assertions. Indeed, the comment merely asserted that the proposed validation requirements would be costly but did not provide any data or other information to support these assertions. FDA notes that in the 2003 reopening, the Agency expressly requested cost information relating to systems validation but no such data were submitted in response to that request.

Accordingly, FDA is not revising the definition of "validation" in proposed § 106.35(a)(4), and thus, § 106.35(a)(4) is included in this interim final rule as proposed.

FDA received a number of comments addressing the scope of the validation requirements.

(Comment 85) Several comments asserted that FDA's validation requirements are overly burdensome, and other comments suggested specific changes to the scope of validation. One comment suggested that the requirements of proposed § 106.35 be limited to the validation of "critical" systems (i.e., proposed § 106.35(b)(1), (b)(3), (b)(4), and (b)(5)) and "critical" hardware and software (i.e., proposed § 106.35(b)(2) and (b)(5)). Another comment stated that although an indiscriminate and across-the-board validation requirement is unnecessarily burdensome, validation of critical systems can be a valuable quality assurance tool for the infant formula manufacturer and that infant formula manufacturers are already validating systems and procedures based upon a risk-based criticality assessment. The comment requested that FDA consider a tiered approach to validation, including such other concepts as verification, qualification, capability studies, challenge testing, and operational testing. For example, HACCP involves both a risk-based criticality assessment and other documented levels of control. The comment suggested that each company should be permitted to decide the levels of validation required, based upon the degree of criticality of each system to assuring the safety and quality of the infant formula produced.

(Response) FDA disagrees that the proposed validation requirements are overly burdensome and declines to limit the scope of these requirements by adding "critical" to the description of systems and of hardware and software.

Although FDA agrees that the process for validation is necessarily related to the level of risk that each component of the system presents, the Agency does not agree that validation should be limited to "critical" systems. A "system" is composed of multiple, interdependent parts, and the proper functioning of the system requires that all system elements are working as intended. Importantly, the comment did not explain how to distinguish "critical" from "noncritical" systems used in the manufacture of infant formula. Infant formula is a sophisticated mixture of ingredients that is intended for use by a vulnerable population as the sole source of nutrition during critically important developmental stages. Given the nature of the product and its intended consumers, it is difficult, if not impossible, to identify a part of the system that is not critical.

Accordingly, all parts of the "system" must be validated— not simply the "critical" pieces—to ensure that the system as a whole operates properly. This approach is consistent with the Agency's position as described in its *Guide to Inspections of Computerized Systems in the Food Processing Industry* (*http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074955.htm*), which states that "as long as the

computerized system controls or records are part of or the entirety of a manufacturing process, the manufacturer is responsible for establishing that the computerized system functions as it was intended to function'' (Ref. 21).

FDA agrees that a manufacturer must determine how to validate its systems to ensure that the system will consistently produce a product meeting predetermined specifications and quality characteristics. The Agency recognizes that the validation process may be more complex for systems that are integral to controlling or affecting those points, steps, or stages where control is necessary to prevent adulteration. Thus, FDA is not specifying how each manufacturer must validate its systems. It is, however, appropriate to require that a manufacturer ensure that any system used to manufacture infant formula is validated by having documented evidence that provides a high level of assurance that the system will produce infant formula that meets applicable specifications and requirements.

(Comment 86) One comment suggested that proposed § 106.35(b)(5) be changed to require revalidation only after a major functional change to a system. The comment explained that this change will avoid unnecessary revalidation as a result of documented operator interface changes that do not change the functionality of the control system.

(Response) FDA disagrees with this comment that seeks to limit the circumstances in which a manufacturer must revalidate a system used to manufacture infant formula. By revalidation, FDA means that the manufacturer must re-establish that, following a modification to a system, the system is functioning as intended. Validation and revalidation of a manufacturer's systems are both fundamental concepts of CGMP applicable to many different types of products, and both are essential to ensuring consistent production of the intended product. Thus, a manufacturer must conduct a validation analysis to determine the extent and impact of the change on the system in response to any change to the system. In fact, a ''major functional change'' requires more extensive revalidation than a change that does not change the functionality of the control system. Nevertheless, revalidation after a change other than a ''major functional change'' is necessary to provide assurance that the system, as changed, will continue to produce consistently a product that satisfies established specifications and quality characteristics. Moreover, FDA advises that the manufacturer must not only analyze the need to validate the individual change but also the validation status of the entire system to ensure that the change did not affect other parts of the system. Based on the validation analysis, the manufacturer should conduct an appropriate level of regression testing to demonstrate that unchanged but vulnerable portions of the system have not been adversely affected.

For these reasons, FDA is not revising proposed § 106.35(b)(5) (recodified as § 106.35(b)(4) in the interim final rule) in response to this comment, and is making only minor editorial changes to this requirement.

(Comment 87) Another comment requested that if FDA intends to require validation of all mechanical and electronic processes used in the manufacture of infant formula, this requirement should not apply retrospectively to processes that have been used successfully for many years. Instead, the comment asserted, validation should apply only to significant changes to equipment or processes that are critical to manufacturing formula in the future. The comment also stated that the manufacturer is in the best position to determine what testing is appropriate for specific pieces of equipment and whether this equipment is critical to infant formula manufacture.

(Response) FDA's response to the previous comment explains why the Agency declines to limit the validation requirement to critical equipment. Similarly, FDA disagrees with the suggestion that validation should not apply retrospectively to systems and processes in place for many years. Although this comment claimed that certain systems have been ''used successfully for many years,'' the comment provided no data or other information to support this assertion. Validation requires a systematic evaluation of a process or system and the development of evidence to show that a system will consistently produce a product within predetermined specifications. The mere operation of a system for a lengthy period without apparent problems is neither systematic nor ''documented evidence'' of adequate function. The manufacturer must ensure that the system it creates (including software and hardware) functions in the way intended and therefore is capable of producing what the manufacturer intends according to required specifications. As noted, FDA is not specifying in the interim final rule how each manufacturer must validate its systems, but is requiring that such systems be validated. This requirement applies to all systems, whether such systems were in place prior to the interim final rule or are established after the effective date of the interim final rule.

(Comment 88) One comment suggested that proposed § 106.35(b)(4) be revised to require that only software-controlled equipment be validated. The comment further stated that this requirement should be changed to require only that the equipment be designed, installed, tested, and maintained in a manner that will ensure that it is capable of performing its intended function and of producing or analyzing infant formula.

(Response) FDA disagrees with this comment. Although various components of a system may, and should, be tested separately, the entire ''system'' (i.e., collection of components, including software and hardware, organized to accomplish a specific function or set of functions in a specified environment) must be validated to ensure that the system, as it is configured and used in the production of infant formula, consistently performs within the pre-established operational limits and consistently produces formula that meets established specifications and quality characteristics. FDA notes that, as defined in proposed § 106.35(a)(3), a ''system'' is the collection of all mechanical and electronic components, as well as all other components, including manual components (such as a manually operated crank), and the operation of such manual components would be evaluated as part of the required validation of the system. The ability of a system to produce the intended product on a consistent basis depends upon the proper functioning of *all* system components. Thus, system validation encompasses all equipment, including mechanical and electronic equipment (which includes computer software.) Therefore, FDA is not revising proposed § 106.35(b)(4) in response to this comment.

(Comment 89) Several comments objected to proposed § 106.35(b)(4) and (b)(5), which would require that all systems be validated before their first use to manufacture commercial product or, in the case of a modified system, before use of the modified system to manufacture commercial product. The comments noted that while most system validation work is conducted prior to the production of infant formula, the first commercial batch should be produced as part of the validation process.

(Response) FDA agrees that a production aggregate of infant formula that is produced as part of the initial validation process of a system may be commercially distributed, provided that the manufacturer determines before release that the production aggregate meets the manufacturer's specifications and otherwise complies with the FD&C Act and FDA's regulations. Similarly, FDA agrees that a production aggregate of infant formula that is produced as part of the revalidation of a system may be commercially distributed, provided that the manufacturer determines before release that the production aggregate meets the manufacturer's specifications and otherwise complies with the FD&C Act and FDA's regulations. Accordingly, FDA is revising proposed § 106.35(b)(4) and (b)(5), which are recodified as § 106.35(b)(3) and (b)(4) in the interim final rule and include minor editorial revisions, to require that infant formula be produced as part of the validation process.

In addition to the comments relating to validation, FDA received comments on several other aspects of proposed § 106.35.

(Comment 90) One comment suggested that the Agency delete the requirement in proposed § 106.35(b)(2) that hardware be routinely calibrated. The comment argued that calibration applies to instrumentation, not hardware.

(Response) FDA disagrees with this comment. The word "hardware" was defined in proposed § 106.35(a)(1) as "all automatic equipment, including mechanical and electronic equipment (including computers) that is used in the production or quality control of a infant formula." As defined, hardware would include any automated instrumentation that can be calibrated. Thus, it is appropriate that proposed § 106.35(b)(2) would require the calibration of hardware. Accordingly, FDA is not deleting the requirement from proposed § 106.35(b)(2) that hardware be routinely calibrated, but is clarifying that calibration applies to hardware that is capable of being calibrated. Thus, § 106.35(b)(1) of the interim final rule reads "A manufacturer shall ensure that hardware that is capable of being calibrated is routinely calibrated according to written procedures, and that all hardware is routinely inspected and checked according to such procedures."

(Comment 91) One comment suggested that the statement "nutrient test results should be used to substantiate the adequacy of the checks required by this section" be added to proposed § 106.35(b)(3).

(Response) FDA is not persuaded to add this statement to proposed § 106.35(b)(3). Nutrient test results alone may not be sufficient to substantiate the adequacy of all checks required by this provision. Although meeting specifications for nutrients may be a part of input/output verification, other factors, such as levels of microorganisms or other contaminants and achieving adequate temperature, may also be a part of verification of the production system.

Assessing the adequacy of can seam measurements illustrates the limitations of nutrient test results for this purpose. A formula manufacturer may use a computerized system to measure and determine the adequacy of container seams. If the system is not confirmed as accurate, errors could be generated by this system and the product could become adulterated due to inadequate container seams. Importantly, nutrient testing could not determine the accuracy of results from this seam measurement system because such testing evaluates the nutritional adequacy of the formula and does not address the adequacy of a formula's packaging. Further, the systems covered by proposed § 106.35 are the automated systems used in the quality control testing of an infant formula. Automated systems used in quality control of an infant formula must also be validated before accurate nutrient test results can be obtained. Thus, FDA declines to add "nutrient test results should be used to substantiate the adequacy of the checks required by this section" to § 106.35(b)(3) in the interim final rule because this would erroneously suggest that nutrient testing is all that is necessary to substantiate the adequacy of the validation required by § 106.35(b)(3).

(Comment 92) One comment suggested that FDA revise the part of proposed § 106.35(b)(3) that states "the degree and frequency of input/output verification shall be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system." The comment stated that the verification must be based on the manufacturer's assessment of the complexity and reliability of the system and the level of risk associated with the safe operation of the system.

(Response) FDA disagrees with this comment because inserting the phrase, "based on the manufacturer's assessment," does not further clarify what is being required. The ultimate purpose of the verification required by proposed § 106.35 is to confirm that formula manufacturing systems will produce a formula that is not adulterated. Although the verification process for more complex systems and systems that operate to control potentially high levels of risk are likely to require more diligence by the manufacturer to ensure the safe operation of the system, the degree and frequency of verification that the manufacturer employs must be sufficient to ensure that the final product is not adulterated. Therefore, FDA is revising proposed § 106.35(b)(3) to clarify the level of effort required. Section 106.35(b)(2) of the interim final rule states "A manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula to ensure that the infant formula is not adulterated." Adding this phrase clarifies that the manufacturer must ensure that the system is able to meet established specifications for any point, step, or stage in the production process where control is necessary to prevent adulteration.

(Comment 93) Regarding proposed § 106.35(c), one comment requested that FDA limit the recordkeeping requirements to critical automatic equipment, as opposed to all automatic equipment.

(Response) As stated in response to Comment 85, FDA declines to limit the validation requirements of the interim final rule to "critical" systems, hardware, and software.

In addition to the revisions to proposed § 106.35 in response to comments, the Agency has made minor editorial revisions in § 106.35 of the interim final rule.

H. Controls To Prevent Adulteration Caused by Ingredients, Containers, and Closures (Proposed § 106.40)

In 1996, FDA proposed in § 106.40 to require that an infant formula manufacturer implement a system of controls designed to prevent adulteration caused by ingredients, containers, and closures. The proposed provisions included standards for ingredients, containers, and closures used for infant formulas, as well as requirements for identification, rejection and acceptance, and storage of these materials.

The Agency received comments on several aspects of proposed § 106.40, which are addressed in this document. In addition to the revisions made in response to comments that are discussed in this document, FDA has made minor editorial revisions in § 106.40 of the interim final rule.

1. Food Ingredients and Food Contact Substances (Proposed § 106.40(a) and (b))

(Comment 94) One comment asserted that proposed § 106.40(a) should be deleted as redundant because, under current law and regulations, it is illegal to use an ingredient in an infant formula that is not GRAS, an approved food additive, or prior-sanctioned for such use.

(Response) As discussed in the response to Comment 1, the Agency is not making changes to § 106.40(a) in response to this comment, and has only made minor editorial changes in § 106.40(a) of the interim final rule.

(Comment 95) Several comments asserted that proposed § 106.40(b) was unnecessarily restrictive in terms of the substances that would be permitted for use in infant formula packaging, including containers and closures. One comment expressed concern that proposed § 106.40(b) would appear to exclude the use of substances in infant formula packaging that are not "food additives" within the meaning of section 201(s) of the FD&C Act (i.e., substances that are not reasonably expected to become a component of food when used as intended). In addition, the comment expressed concern that proposed § 106.40(b) would prohibit the use of substances reviewed under 21 CFR 170.39 for use in food-contact material and exempted from the requirement of a food additive regulation. This comment also contended that all packaging materials authorized by a prior sanction issued by the U.S. Department of Agriculture (USDA) should be allowed in infant formula packaging.

(Response) FDA did not intend to limit permissible infant formula packaging to substances regulated as food additives. To the extent that use of a food packaging material for infant formula packaging is exempt under § 170.39, FDA agrees such substance would be permissible in infant formula packaging. Similarly, although FDA is not aware of any prior sanction issued by USDA for a substance that could be used in infant formula packaging, if a prior sanction exists, a substance used in accordance with such prior sanction would be lawful. Also, to the extent that a substance in food packaging is not reasonably expected to become a component of food, the substance is not a food additive under section 201(s) of the FD&C Act and thus, could be lawfully used in infant formula packaging without prior approval. Finally, proposed § 106.40(b) recognized that a substance authorized for use as an "indirect food additive" could be lawfully used in infant formula packaging. As a result of amendments made to section 409 of the FD&C Act by the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115), food packaging materials are generally now regulated as "food contact substances." Thus, FDA agrees that the rule should recognize that a food contact substance that is the subject of an effective notification under section 409(h) of the FD&C Act may be lawfully used in packaging for infant formula.

Thus, in response to these comments and the FDAMA amendments, FDA is clarifying proposed § 106.40(b) to identify all substances that may lawfully be used for infant formula containers, closures, and packaging. Section 106.40(b) of the interim final rule lists all substances that may lawfully be used in food packaging for infant formula.

(Comment 96) One comment suggested that FDA list in § 106.40(b) substances that are exempted from the requirement of a food additive listing regulation under § 170.39.

(Response) FDA does not agree that the Agency should list in § 106.40(b) of the interim final rule those substances that FDA has exempted from the requirement of a food additive listing regulation under § 170.39. This information is continually changing, and FDA's Web site has current lists of the substances exempted under § 170.39, *http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm093685.htm*, and the food contact substances that are the subject of an effective notification, *http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm*.

2. Written Specification for Ingredients, Containers, and Closures (Proposed § 106.40(d))

Several comments objected to proposed § 106.40(d), which would require an infant formula manufacturer to develop written specifications for the acceptance or rejection of ingredients, containers, and closures ("the materials") to be used in infant formula manufacturing.

(Comment 97) One comment objected to several statements in the 1996 proposal, including FDA's statement that "indigenous" nutrients should be included in ingredient specifications and standards for acceptance or rejection (61 FR 36154 at 36167). The comment argued that testing for endogenous nutrients in these cases is not for acceptance or rejection of the ingredient, but to determine the actual nutrient levels that can be factored into specific batch formulations.

(Response) As discussed previously in this document in section V.C.1, FDA is persuaded by the comments to revise § 106.40(d) in the interim final rule to delete the requirement that any ingredient, container, or closure that does not conform to specifications must automatically be rejected. The Agency believes that this change responds, at least in part, to the comment objecting to statements in the 1996 preamble that manufacturers must establish, and test for, levels of endogenous nutrients in formula ingredients.

FDA disagrees with this comment to the extent that it objects to the requirement that the proposed rule would require a formula manufacturer to establish specifications for the nutrient content of formula ingredients and a process to assess whether such specifications have been met. These procedures may include reliance on a supplier's guarantee or certification that an article conforms to specifications or a laboratory analysis by the formula manufacturer that demonstrates that the article conforms to established specifications. Even where a formula manufacturer relies on a guarantee, FDA expects that the ingredient will conform to the specifications set by the manufacturer and that the manufacturer has a means to evaluate the guarantee or certification, such as periodic chemical analysis of the ingredient.

A manufacturer's specifications should include specifications for endogenous nutrients in formula ingredients because such specifications are one method of ensuring both that the required nutrients will be present in the infant formula at or above the established minimum level and that any nutrient for which there is an established maximum level is not present in the formula at a level that would cause the product to be adulterated. Chemical analysis for such endogenous nutrients is the means by which a manufacturer is able to determine the nutrient levels actually present, which information may be factored into a specific production aggregate's formulation.

Although there is no requirement that the manufacturer test every ingredient for all nutrients as suggested in the comment, section 412(b)(3)(B) of the FD&C Act requires that manufacturers test each nutrient premix for each nutrient that the manufacturer expects to be supplied by the premix to ensure that the premix complies with its specifications or the certification by the

premix supplier. Accordingly, the FD&C Act requires that a manufacturer test each nutrient premix, but the FD&C Act does not require testing the premix for nutrients not intended to be supplied by the premix.

(Comment 98) One comment asserted that infant formula manufacturers have an extensive history in the use of condensed skim milk such that they can predict endogenous nutrient levels within a narrow range. The comment argued that because of this experience with this ingredient and the fact that the condensed skim milk can provide 100 percent of several of the final product's nutrients, there is no need to assay the ingredients for specific batch formulations. The comment also argued that because all nutrients required to be present in infant formula are tested and assured in each batch as required by the Infant Formula Act, any problems would be detected through routine, legally mandated in-process and finished product testing.

(Response) Section 106.40(d) of the interim final rule does not specify which nutrients in which formula ingredients must be the subject of manufacturer specifications and does not require that ingredients be tested for endogenous nutrients. FDA agrees with the comment that an infant formula manufacturer's history of use of an ingredient may help determine what endogenous nutrients should be included as an ingredient specification and when testing is necessary to confirm a supplier's assurance that the manufacturer's ingredient specifications are met. FDA views endogenous nutrient specifications as one method of ensuring both that the required nutrients will be present in the infant formula at the appropriate level and that nutrients that have maximum levels under § 107.100 will not be present in the formula at levels that would cause the product to be adulterated. Testing of endogenous nutrients can serve to confirm that the nutrients are in the ingredient in the amount anticipated by the manufacturer and to ensure that the infant formula will have the required levels of nutrients. The example given in the preamble to the 1996 proposal (61 FR 36154 at 36167) was the level of sodium determined in the protein ingredient, sodium caseinate. The maximum level of sodium that can legally be in an infant formula is 60 mg/100 kilocalorie (kcal). The level of sodium in the sodium caseinate will affect how much sodium can be added to the formula from other sources before this legally mandated sodium limit is violated.

Although the interim final rule does not require testing ingredients for endogenous nutrient levels, it is very useful for manufacturers to know the endogenous nutrient content of the ingredients so that the infant formula is manufactured with all the required nutrients within required ranges and adjustments that may be needed during processing may be better anticipated. Use of routine in-process and finished product testing is valuable because it can help detect problems with the levels of required nutrients prior to distribution. Testing for endogenous ingredients may reduce the need for adjustments during processing, which can provide the manufacturer with added efficiency, reduced costs, and more robust adherence to CGMP. Indeed, a manufacturer may find through experience that the best way to ensure that the final product will meet all specifications is to measure certain nutrients in ingredients before using them in the production of infant formula.

(Comment 99) One comment stated requiring that ingredients be tested for all endogenous nutrients would have a significant impact on laboratory space, manpower, operating costs, and potentially quality, with no increased assurance of benefit to infants consuming the final product.

(Response) As noted previously in this document, FDA is requiring under § 106.40(d) of the interim final rule that any failure to meet specifications be investigated to ensure that the failure does not lead to the release into the marketplace of an adulterated infant formula. FDA is not requiring that the manufacturer test all formula ingredients for all endogenous nutrients. Importantly, however, endogenous nutrient testing is one means to limit final product rejection, reformulation, or reprocessing and thus, the costs of such testing must be balanced by potential costs of rejection, reformulation, or reprocessing. That is, a manufacturer should consider that the costs of formula adjustments during or at the end of processing might be avoided by chemical analysis of ingredients because such an approach may offset possible costs related to testing the endogenous nutrient content.

(Comment 100) One comment also objected to the suggestion in the preamble to the 1996 proposal that included testing for contaminants in the ingredient specifications and standards for acceptance or rejection of the material except as provided in compendial standards such as United States Pharmacopeia (USP) (*http://www.usp.org*). The comment argued that this suggestion is inappropriate and unworkable and that there are significant questions to be considered, such as the selection of contaminants to test for in each ingredient, the determination of acceptable/unacceptable levels, and detection versus quantification scenarios. The comment further argued that even if one were to address these questions, the inclusion of routine contaminant testing would be grossly impractical due to the sophistication of the testing involved and the exorbitantly high costs associated with compliance. The comment stated that the testing requirements for ingredients, containers, and closures should be determined by the manufacturer.

(Response) As explained in section V.C.1 of this document, FDA has revised proposed § 106.40(d) by removing the proposed requirement that an ingredient, container, or closure that fails specifications shall be automatically rejected for use in formula manufacturing and, instead, to provide that an ingredient, container, or closure that fails to meet a specification, as well as any formula that could be affected by the deviation, shall be quarantined pending a formal, documented review and material disposition decision. The Agency recognizes that a failure to conform to a specification does not necessarily mean that the infant formula manufactured using the ingredient, container, or closure will be adulterated and thus, should not be automatically rejected for use in formula manufacturing. In the interim final rule, FDA has made additional revisions to the proposed provisions to ensure that deleting the automatic rejection provision will nevertheless result in adequate public health protection by requiring that each manufacturer establish a robust procedure to investigate any deviation from specifications so that the manufacturer can credibly determine whether the deviation from specifications will result in adulteration of infant formula. The revisions to the proposed requirements will ensure that there is a documented review of the deviation, that records of such documented review are established and maintained, and that affected materials are quarantined pending a decision about their appropriate disposition. Therefore, this comment has been addressed to the extent that it relates to the need for a specification to determine "acceptance or rejection" of ingredients, containers, and closures.

FDA agrees with the comment that the infant formula manufacturer is responsible for determining whether contaminant testing of formula

ingredients is warranted and if so, for which contaminants. In the 1996 proposal, FDA did not specify the contaminants for which a manufacturer must test or when such testing must occur because the Agency believes that formula manufacturers are likely to be more aware of which contaminants may be present in their particular ingredients and that may adulterate or lead to adulteration of formula.

(Comment 101) One comment suggested that FDA add the phrase "as components" and the phrase "and packaging" to proposed § 106.40(d) to require manufacturers to develop written specifications for ingredients, containers, and closures used as components in infant formula manufacturing and packaging.

(Response) FDA declines to adopt the suggestion in this comment because the Agency considers that it is understood that the ingredients, containers, and closures referred to in proposed § 106.40 for which the manufacturer must develop written specifications are those used by such manufacturer in its formula production operation. Indeed, this is a reasonable interpretation because these are the ingredients, containers, and closures over which the manufacturer exercises control, including the authority and obligation to establish and apply specifications for such materials.

(Comment 102) One comment suggested that proposed § 106.40(e)(3) should be revised to permit the reconditioning, under certain conditions, of materials that have been rejected for use in infant formula production. The comment did not specify under what conditions it thought reconditioning should be allowed.

(Response) As discussed previously in this document in response to Comment 38, § 106.40(d) of the interim final rule establishes reconditioning of an ingredient, container, or closure that fails to meet a specification as one of the three alternative dispositions that may result from the documented review that is required when any such material does not conform to a manufacturer's specifications.

3. Option To Reject Ingredients, Containers, or Closures (Proposed § 106.40(f))

(Comment 103) One comment requested that proposed § 106.40(f) be modified to permit rejection of ingredients, containers, or closures that fail to meet a specification as well as for the retesting or reexamination of such deviant materials.

(Response) As discussed in response to comment 38, § 106.40(f) of the interim final rule requires a documented review and material disposition decision and such decision may be to reject an ingredient, container, or closure that does not conform to the manufacturer's specifications, to reprocess or otherwise recondition and then test or reexamine such material to determine whether it should be approved and released for use, or simply to approve and release for use without reconditioning.

(Comment 104) Another comment agreed that the requirement to retest or reexamine any ingredient, container, or closure, if it is found by the infant formula manufacturer to have been exposed to adverse storage conditions, is reasonable. However, the comment contended that this requirement should only apply when the manufacturer has knowledge of the potentially adverse conditions. The comment suggested that to document control of all storage areas, additional recording charts might be needed to provide continuous monitoring.

(Response) Consistent with changes elsewhere in the interim final rule and discussed in section V.C.1, FDA has revised proposed § 106.40(f) to provide for a documented review and material disposition decision in the circumstances covered by this provision. Also, the Agency is not persuaded that the requirement of proposed § 106.40(f) should only apply when the manufacturer has actual knowledge of potentially adverse conditions affecting an ingredient, container, or closure. A manufacturer has a responsibility, as part of CGMP, to quarantine an ingredient, container, or closure when that manufacturer has a reasonable basis to believe that the ingredient, container, or closure may have been exposed to adverse conditions. For example, a manufacturer must quarantine and conduct a documented review and make a material disposition decision when the manufacturer has information relating to where and when such materials were held, which information reasonably suggests that the integrity of the materials may have been compromised. A formula manufacturer has the overarching responsibility to ensure that its infant formula is not adulterated, which responsibility includes ensuring that ingredients, containers, or closures are not exposed to conditions that may result in the production of an adulterated formula product. After a documented review and material disposition decision to release, these ingredients, containers, and closures must remain suitable for use in the manufacture of infant formula so that when such materials are used in formula production, the materials continue to conform to the manufacturer's specifications. In response to this comment, the Agency is revising proposed § 106.40(f) to clarify that an ingredient, container, or closure must also be quarantined when a manufacturer reasonably believes that an ingredient, container, or closure may have been exposed to adverse conditions.

I. Controls To Prevent Adulteration During Manufacturing (Proposed § 106.50)

In 1996, FDA proposed to require in § 106.50 that an infant formula manufacturer implement a system of controls designed to prevent adulteration during the production of infant formula. The proposed provisions included requirements for use of a written master manufacturing order; for control and examination of raw and in-process ingredients; for identification of the contents of compounding and storage containers; processing lines and major equipment; for controls to ensure required nutrient levels and to prevent contamination of formula; for equipment monitoring; and for control of rejected in-process materials.

The Agency received comments on several aspects of proposed § 106.50, which are addressed in this document. In addition to the changes discussed in this document made in response to comments, § 106.50 of the interim final rule includes minor editorial revisions.

1. Identification of the Contents of Storage Containers, Processing Lines, and Major Equipment (Proposed § 106.50(c))

Several comments requested clarification of proposed § 106.50(c), which would require a manufacturer to identify the contents, including the processing stage and the lot or batch number of a batch of infant formula, of all compounding and storage containers, processing lines, and major equipment used during the production of a batch (production aggregate) of an infant formula.

(Comment 105) One comment requested clarification of the meaning of "identify" in proposed § 106.50(c). The comment objected to physically labeling these items because, the comment asserted, infant formula manufacturers use multitudes of equipment and lines in the production of infant formula and physical labeling would require a significant increase in manpower to apply and remove labels several times

daily to accomplish this task with no benefit to the operation. However, the comment stated that it would be reasonable to require a system that would permit determination of the location and movement of each batch of infant formula. The comment suggested alternative language that would require a manufacturer to establish a system that permits the manufacturer to determine the major equipment systems used during the production of a batch of infant formula.

(Response) FDA considers that it is necessary to clarify the purpose of proposed § 106.50(c). The Agency did not intend the term "identify" in proposed § 106.50 to require that a manufacturer physically place a label identifying the contents, processing stage, and production aggregate number on each piece of equipment used to manufacture a particular production unit of infant formula. Although FDA agrees that this method would satisfy the requirements of proposed § 106.50(c), it is not the only means by which a manufacturer could comply with proposed § 106.50(c). To clarify this requirement, the Agency has revised § 106.50(c) in the interim final rule to require that a manufacturer establish a system (i.e., a collection of components organized to accomplish a specific function or set of functions in a specified environment) of identification for the contents of all compounding and storage containers, processing lines, and major equipment used during the manufacture of a production unit or a production aggregate of an infant formula. As such, this provision gives a manufacturer flexibility to design its production tracking system. Thus, the requirement in § 106.50(c) could be met, for example, by establishing a computerized system that makes it possible to track a particular production unit or production aggregate of infant formula throughout all stages of the manufacturing process, permitting the identification of the contents of all compounding and storage containers, processing lines, and major equipment used during the manufacturing of a specific production aggregate of infant formula. As noted, the comment agreed that it is reasonable to require establishment of a system that permits determination of the location and movement of each production aggregate.

FDA declines to adopt the alternative language proposed by this comment because it does not accurately capture the purpose of the proposed requirement. The purpose of proposed § 106.50(c) is to require a manufacturer to establish a system to identify the *contents* of compounding and storage containers, processing lines, and various pieces of equipment used during the manufacture of a particular production aggregate of infant formula and not to identify the major equipment systems used during a particular production run. This purpose was recognized in the preamble of the 1996 proposal: "[Proposed § 106.50(c)] will enable the manufacturer to accurately determine the status of all batches of infant formula during all stages of the manufacturing process, will help to prevent mix-ups in the addition of ingredients to the formula, and will facilitate prompt action by the manufacturer if any problems in processing are identified. For example, identifying that a particular storage container contains a batch of formula that has not yet had all ingredients added to it will prevent a manufacturer from inadvertently final-stage packaging the product and thus will help to ensure that adulterated product is not introduced into interstate commerce" (61 FR 36154 at 36169).

(Comment 106) One comment stated that it should be necessary to identify the processing lines used in the manufacture of infant formula only if the manufacturing facility is processing different types of infant formula or non-infant formula products simultaneously because there is increased potential for cross-contamination or comingling of different products. In such circumstances, the comment argued, processing lines should be identified.

(Response) FDA disagrees with the comment that the requirement of proposed § 106.50(c) should apply only when a firm is simultaneously manufacturing more than one type of infant formula product or a formula product and a non-formula product. The purpose of the requirement to establish an identification system is to ensure that both finished product and in-process material can be fully identified, including by the unique number associated with its production aggregate. This will ensure that if a problem develops with a formula product necessitating a recall, the affected product can be specifically identified and the recall structured as narrowly as possible. A narrowly targeted recall is more readily managed by a formula company and overseen by FDA and also reduces the likelihood of a product shortage from an overly broad recall.

Moreover, as noted in the preceding comment, infant formula processing facilities often contain a multitude of equipment, storage tanks, and processing lines; those processing lines may include liquid component lines, in-process lines, and finished product lines, as well as ancillary lines such as cleaning solution lines, steam lines, and water lines. Regardless of whether a facility processes different types of infant formulas, processes non-formula products simultaneously with infant formula, or processes only one type of infant formula, the content of these lines, tanks, and equipment must be identified in some way to ensure that such contents are not mishandled or misused. The example from the 1996 preamble cited in the response to the preceding comment illustrates clearly why content identification is essential even when a facility produces only a single type of formula. Importantly, under § 106.50(c) of the interim final rule, a manufacturer has the discretion to select its content identification system.

2. Controls To Ensure the Nutrient Levels and Lack of Contaminants in Formulas (Proposed § 106.50(d))

(Comment 107) One comment agreed that the intent of proposed § 106.50(d) is sound and is rightfully a part of the CGMP regulations for infant formula but objected to what it characterized as the prescriptive nature of proposed § 106.50(d)(1) through (d)(4) and requested that these specific paragraphs be deleted. The comment argued that FDA should allow individual manufacturers to determine the best and most economical approach to producing high quality infant formulas that meet the nutrient requirements of § 107.100 and do not contain contaminants. The comment contended that FDA only needs to define the goal and general intent of this section and not specify exact parameters that a manufacturer must follow. The comment expressed concern that defining exact parameters could unintentionally prevent manufacturers from using other production methods that could result in an acceptable product. The comment suggested that the manufacturer should document its intended approach, as well as compliance with its own designated control systems.

(Response) FDA disagrees that the requirements in proposed § 106.50(d)(1) through (d)(4) are overly prescriptive. Indeed, one benefit of this interim final rule is that it informs new infant formula manufacturers of the controls that must be established in a proper infant formula manufacturing operation. The points identified in proposed § 106.50(d)(1), (d)(2), (d)(3), and (d)(4) are those at which control is necessary to produce a formula that is homogeneous, that is not contaminated, that will not undergo nutritional

deterioration, and the containers of which will remain properly sealed. Controls at these points are essential to the production of any formula to ensure that it is not adulterated, a conclusion not disputed by the comment. Importantly, however, the manufacturer has the authority, responsibility, and flexibility to determine the parameters for each control point, and these parameters are, in part, based on the manufacturer's knowledge and experience. Thus, the manufacturer has the flexibility to determine the specific time, temperature, and speed for mixing; the steps needed in a spray-drying process to prevent microbial and other contamination; the extent of air removal needed from finished product to prevent nutrient deterioration; and procedures for ensuring proper seal of containers. Because the comment did not explain why control is not necessary at the points identified in proposed § 106.50(d)(1) through (d)(4), FDA is not revising proposed § 106.50(d) in response to this comment.

3. Removal of All Air From Containers of Infant Formula (Proposed § 106.50(d)(3))

(Comment 108) One comment objected to proposed § 106.50(d)(3), which requires "the removal of air from the finished product to ensure that nutrient deterioration does not occur." The comment explained that it is not technically feasible to remove all "oxygen" to ensure that nutrient deterioration does not occur, and suggested that this provision be revised to require "the removal of oxygen from the finished product to a level that will avoid deterioration below an acceptable level of nutrients throughout the shelf life of the product." Another comment stated that if a manufacturer could package an infant formula without the removal of air and still meet the nutritional and quality factors throughout the shelf-life of the product, FDA should permit this approach.

(Response) The Agency recognizes that it may not be possible to remove all of the air from finished product containers. Importantly, however, the manufacturer must remove or control the amount of air in the container to prevent deterioration of nutrients. When the requirement of proposed § 106.50(d)(3) is read in conjunction with the stability testing requirements of proposed § 106.91(b), air removal must be sufficient to ensure that the nutrients continue to meet the levels required by section 412(i) of the FD&C Act throughout the shelf life of the product. Each manufacturer must decide the extent to which air must be removed from its finished product containers to ensure nutrient stability. Further, proposed § 106.50(d)(3) is consistent with the regulations on thermally processed low-acid foods packaged in hermetically sealed containers (part 113), which require that the "exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed" (§ 113.81(d)). Liquid infant formulas that are low-acid canned foods must comply with part 113; one purpose of the process for such liquid formulas is to ensure stability of a formula's nutrients throughout the shelf-life of the formula. Accordingly, FDA is not modifying proposed § 106.50(d)(3) in response to these comments, and § 106.50(d)(3) is included in this interim final rule as proposed.

4. Controls on Rejected In-Process Materials (Proposed § 106.50(f))

(Comment 109) One comment suggested deleting or revising proposed § 106.50(f)(3), which would require a manufacturer to establish controls to ensure that rejected in-process materials meet the appropriate specifications, if reprocessed, before being released for use in infant formula. The comment argued that this section could be deleted if the definition of specifications suggested in the comment were adopted by the Agency because the proposed definition of specifications addresses the situation described in proposed § 106.50(f)(3). The comment recommended the following definition of "specifications:" "Specifications means quality control limits or standards for raw materials, in-process materials, and finished product, which are established by the manufacturer for purposes of controlling quality and consistency for infant formula. Failure to meet an established specification requires a documented review and material disposition decision."

(Response) The response to Comment 35 addresses the request that the rule include a definition of "specifications." For the reasons stated in that response, FDA declines to add a definition of "specifications" to the interim final rule. Because the request to delete proposed § 106.50(f)(3) relies on a separate suggested change that FDA declines to make, Comment 109 has been addressed.

(Comment 110) One comment asserted that proposed § 106.50(f)(3) could be interpreted as requiring that all out-of-specification in-process materials be rejected.

(Response) As discussed previously in this document, FDA did not intend all out-of-specification in-process materials to be rejected and has revised proposed § 106.50(f) to be consistent with revisions made elsewhere in the interim final rule, including §§ 106.6(c), 106.40(d), 106.40(e), 106.40(f), and 106.70, related to a failure to meet a specification.

The distinction between "out-of-specification material" and "rejected material" is clear in light of the revisions made elsewhere in the interim final rule. As noted previously in this document, the interim final rule revises § 106.6(c)(4) to require that, where there is a failure to meet any specification established under § 106.6(c)(1), an individual qualified by education, training, or experience conduct a documented review and make a material disposition decision to reject the affected article (i.e., material or product), reprocess or otherwise recondition the affected article, or approve and release the article for use or distribution. Thus, one possible outcome is that the out-of-specification in-process material is not rejected and is released for use in formula without the need for reprocessing or other reconditioning. Another possible outcome of the documented review and material disposition decision is that the non-conforming article is rejected. Additionally, if appropriate, the out-of-specification material may be reprocessed, and if successfully reprocessed, could be used in an infant formula. Thus, under the terms of the interim final rule, out-of-specification material is not necessarily required to be rejected. However, if in-process material is rejected following the documented review and material disposition decision required by § 106.6(c), § 106.50(f)(4) requires that any such material be clearly identified as rejected and be quarantined. Likewise, under § 106.50(f)(2) of the interim final rule, in-process materials that are pending a documented review and disposition decision must be clearly identified as such and be controlled under a quarantine system to prevent their use prior to any disposition decision. Additionally, if an in-process material is reprocessed, it must undergo another documented review and material disposition decision to determine whether the in-process material that has been reprocessed may be released for use in infant formula.

Accordingly, to clarify the required controls for in-process material that fails to meet specifications, including controls for rejected in-process material, FDA is revising proposed § 106.50(f) as discussed previously in this document in section V.C.1.

J. Controls To Prevent Adulteration From Microorganisms (Proposed § 106.55)

In 1996, FDA proposed to require that infant formula manufacturers establish controls to prevent the adulteration of formula from microorganisms. Specifically, proposed § 106.55(a) would have required that a manufacturer of liquid infant formula comply with the procedures in part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers). Proposed § 106.55(b) would have required that a manufacturer of powdered infant formula test representative samples of every batch (production aggregate) at the final product stage and before distribution to ensure that the formula meets microbiological quality standards, which standards were set out in proposed § 106.55(c). Proposed § 106.55(c) would have established seven microbiological standards: aerobic plate count (APC), coliforms, fecal coliforms, *Salmonella, Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus.* Under proposed § 106.55(c), if the M value (defined as the maximum allowable number of organisms present in 1 g of dry formula, expressed as "colony forming unit per gram" (CFU/g) or "most probable number" (MPN/g)), for the microbe was exceeded, the infant formula would have been considered adulterated under sections 402 and 412 of the FD&C Act. Proposed § 106.55(d) would have required a manufacturer to make and retain records relating to the testing of infant formulas for microbial contamination.

Thereafter, in 2003, FDA reopened the comment period to receive new information based on the 2002 and 2003 meetings of the FAC and two of its subcommittees that considered, among other issues, microbiological standards for *E. sakazakii* (*Cronobacter* spp.)[3] and other microorganisms in powdered infant formula (68 FR 22341). At that time, the Agency requested comments on whether the final rule should include a microbiological standard for *E. sakazakii* (*Cronobacter* spp.) and if so, what that standard should be. Concerns about *Cronobacter* spp. stemmed from the 2001 death of one of ten infants made ill from consuming formula consisting of sterile water and contaminated powdered infant formula (68 FR 22341 at 22342). The Agency also requested comments on additional changes to the microbiological standards proposed in 1996 and on whether formula for preterm and newborn infants should be subject to more strict microbiological requirements.

FDA subsequently reopened the comment period in 2006 to consider the recommendations from an FAO/WHO expert consultation, the report of which included a risk assessment model and data used for that model that became available after the 2003 reopening. The Agency announced that, based on its review of the expert reports, it had tentatively determined to establish a standard for *Cronobacter* spp.; that the appropriate standard for *Cronobacter* spp. would be negative in 30 × 10 g samples and, for *Salmonella* spp., negative in 60 × 25 g samples; that manufacturers would be required to test representative samples of each production aggregate (batch) of powdered infant formula for the two pathogens; and that testing for aerobic plate count (APC) and the five remaining microorganisms identified in the 1996 proposal (coliforms, fecal coliforms, *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus)* would not be required. The Agency specifically requested comments on two issues related to the microbiological quality of powdered infant formula: whether FDA should establish a standard for *Cronobacter* spp. in powdered infant formula of negative in 30 x 10 g samples and whether FDA should finalize microbiological standards for APC, coliforms, fecal coliforms, *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus.*

The Agency received comments on microbiological controls in response to the 1996 proposal and in response to the 2003 and 2006 reopenings. This section addresses those comments.

1. Microbiological Requirements for Liquid Infant Formula (Proposed § 106.55(a))

FDA received no comments opposing this proposed provision. On its own initiative, FDA is revising proposed § 106.55(a) to clarify that liquid infant formulas that are acidified foods are required to comply with the regulations in part 114 ("Acidified foods"). In addition, for clarity and consistency with the remainder of the interim final rule, FDA is making minor editorial changes and is redesignating proposed § 106.55(a) in this interim final rule as § 106.55(b) to state: "A manufacturer of liquid infant formula shall comply, as appropriate, with procedures specified in part 113 of this chapter for thermally processed low-acid foods packaged in hermetically sealed containers and part 114 of this chapter for acidified foods."

FDA notes that § 106.55(a) of the interim final rule is discussed in section J.2.a.ii.

2. Microbiological Requirements for Powdered Infant Formula (Proposed § 106.55(b) and (c))

As a result of the reopening of the comment period in 2003 and 2006, the Agency's tentative conclusions about appropriate microbiological testing requirements (proposed § 106.55(b) and (c)) have been substantially revised and are discussed in this document.

a. *General comments.*

i. *Final product stage testing.*

(Comment 111) Several comments suggested that FDA re-evaluate the need for finished product microbiological testing of all lots (production aggregates) of infant formula to determine whether such testing will provide significantly enhanced safety when an effective in-process control system is in place.

(Response) FDA disagrees with the suggestion of this comment.

First, the comment appears to misunderstand the proposed requirements for microbiological testing of finished product at the final product stage. In particular, liquid infant formulas (concentrates and ready-to-feed formulas) must comply with the requirements for thermally processed, low-acid foods packaged in hermetically sealed containers (in part 113) or with requirements for acidified foods (in part 114), which do not require final product stage microbiological testing. Part 113 focuses on ensuring that commercial sterility[4] is achieved in thermal processing and packaging; part 114 ensures that commercial sterility is achieved through acidification, thermal processing, and packaging. Processing an infant formula consistent with part 113 or part 114 ensures the destruction of vegetative pathogens, including *Cronobacter* spp. and *Salmonella* spp.

Second, FDA acknowledges that proposed § 106.55(b) would have

[3] As noted previously in the document, in 2008, the taxonomy of *Enterobacter sakazakii* was reclassified to include all the species that were pathogenic into a new genus named *Cronobacter* spp. (Ref. 1).

[4] FDA's regulations on acidified foods, 21 CFR 114.80 states that "acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user." As used in this interim final rule, the term "commercial sterility" includes an acidified food that has been thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user.

established microbiological standards for powdered infant formulas and would have required representative samples from every production aggregate of powdered infant formula to be tested, at the final product stage and before distribution, to ensure that the production aggregate meets the established standards. The comment included no data or information to support its suggestion that an effective in-process control system would eliminate the need for end-product testing. The purpose of final product stage testing is to ensure the microbiological safety of each production aggregate of infant formula. In addition, however, final product stage testing serves to verify that the manufacturer's food safety control system is operating effectively to prevent microbial contamination of formula during processing because, to the extent that such testing shows finished product contamination, the manufacturer is put on notice that its system of controls is not functioning effectively.

(Comment 112) One comment stated that based on knowledge of factors associated with *E. sakazakii* (*Cronobacter* spp.) infections (such as abusive temperatures and poor storage conditions), relying on end-product microbiological testing as a control strategy for this microorganism is not a dependable approach to preventing illness. Several other comments suggested that education concerning formula preparation and handling, or additional labeling, is more likely to reduce the risk of infection than finished product testing. One comment suggested that FDA issue guidelines on the correct preparation of formula.

(Response) FDA disagrees with these comments to the extent that they suggest that education concerning formula preparation and handling should replace final product stage testing. First, the comment does not dispute that powdered infant formula itself can be a source of *Cronobacter* spp. contamination. Although the data on surveys of *Cronobacter* spp. in powdered infant formula show that the percent of samples found positive for the pathogen have decreased over the past years as manufacturers have implemented stricter controls in the processing environment (Ref. 3, Table 4), the risk that the organism will be present in finished formula still exists.

Cronobacter spp. have been described as "a severe hazard for restricted populations, [resulting in] life threatening or substantial chronic sequelae of long duration" by the International Commission for Microbiological Specifications for Foods (ICMSF 2002) (Ref. 22). *Cronobacter* spp. have been identified as the etiological agent in neonatal meningitis, septicemia, and necrotizing enterocolitis, and are considered emerging opportunistic pathogens (Ref. 23 and 24). *Cronobacter* spp. have caused meningitis resulting in brain abscess and ventriculitis (inflammation of the cerebral ventricles) with a very high associated mortality rate in neonates and infants (Refs. 23 and 25). Survivors of *Cronobacter*-induced meningitis suffer life-long mental and physical developmental delays (Ref. 23). Although there has been continued study of this pathogen and further characterization, the dose required to cause infection has yet to be determined (Ref. 24). Given the absence of a documented infectious dose and the severity of *Cronobacter* spp. infections in infants, even a low risk of such contamination of infant formula from the production environment must not be tolerated.

An important objective of CGMP is to identify points in product processing where there is a risk of adulteration and implementing controls to prevent contamination that adulterates the product. This objective is captured generally in § 106.6(b) of the interim final rule and specifically in § 106.55(a), which, as discussed in this document, has been added to § 106.55 of the interim final rule. Implementing a standard for *Cronobacter* spp., which includes testing of the final production aggregate, complements these efforts directed at system control by providing a separate mechanism to verify that food safety measures and system process controls are producing an infant formula that is not adulterated.

It is also important to note that there have been multiple efforts by various external groups to alert consumers and health professionals about the risk of illness from *Cronobacter* spp. and powdered infant formulas contaminated with this pathogen. For example, in 2011, the American Dietetic Association (ADA) published an updated book titled "Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities" (Ref. 26). The International Formula Council (IFC) published a pamphlet for health professionals, which was based on the ADA book; the IFC guidelines are available at *www.infantformula.org/for-health-professionals* (Ref. 27). The American Academy of Pediatrics (AAP) also published an article on infant formula safety that provides recommendations on food safety practices for powdered infant formula (Ref. 28). Manufacturers of powdered infant formula have developed educational materials for consumers and made changes to their labels to include directions for the safe preparation and storage of infant formula. In addition, the USDA provides guidance to participants in the USDA Women, Infants, and Children (WIC) program on safe preparation and storage of infant formula *www.nal.usda.gov/wicworks/Topics/FG/Chapter4_Infantformulafeeding.pdf* (Ref. 29, p. 91).[5] All of these programs contribute to the overall food safety efforts to prevent foodborne illness from contaminated powdered infant formula.

(Comment 113) Some comments suggested that point-of-use contamination from poor preparation practices represents the most significant risk of *E. sakazakii* (*Cronobacter* spp.) infection for infants consuming formula.

(Response) FDA is not aware of data that would refute or corroborate this point. Moreover, the comment did not provide any data to support this assertion. There is always a potential risk that microbial contamination may occur during food handling. However, that possibility does not mean that there is no need to ensure that a packaged infant formula product does not exceed microbial limits before distribution from the processing plant. The responsibility for food safety falls at every point along the food chain, which begins with manufacturing. Better controls used by the manufacturer to minimize contamination during processing contribute substantially to reducing the risk of illness at point of use.

(Comment 114) One comment stated that the need for end-product microorganism testing should be determined by the manufacturer.

(Response) FDA disagrees with this comment. Infant formula is intended for consumption by a vulnerable population and, as discussed previously in this document, infants are at risk of significant morbidity or mortality from an infection caused by *Cronobacter*. Illness caused by *Salmonella* spp. (salmonellosis) has long been associated with contaminated dried milk products. Non-typhoidal serovars (NTS) of *Salmonella*, such as *Salmonella enterica*, have also been found in infant formulas and are capable of causing invasive disease. In the reported outbreaks of Salmonella infection associated with powdered infant formula, the organism was found at low

[5] Significantly, according to the USDA, Economic Research Service, WIC participants now account for over half of all infant formula sold in the United States (Ref. 30), and WIC participants use powdered infant formula almost exclusively.

levels in the unreconstituted powdered formula. The incidence of salmonellosis among infants is higher than in all other age groups and is considered a public health problem (Ref. 31). Infants younger than 1 year of age are reported to have an infection rate of 120/100,000 population in the United States (Ref. 32). The symptoms associated with salmonellosis range from dehydration to bloody diarrhea requiring hospitalization, sepsis, and death. Complications from NTS include bacteremia (bacterial bloodstream infection), enterocolitis (inflammation of the mucus membrane of the small intestine or colon), meningitis (inflammation of the membranes covering the brain or spinal cord), and osteomyelitis (inflammation of bone due to an infection). Indeed, the threat to the health of infants from consuming powdered infant formula contaminated with these pathogens has been recognized not only by the FDA, but by the international community as well. Accordingly, due to the severity of illness associated with contamination, FDA has concluded that the frequency and degree of end-product testing must be prescribed by the Agency in the interim final rule and not simply left to the discretion of each formula manufacturer. However, because the testing specified in § 106.55 of the interim final rule is the minimum necessary, a formula manufacturer is free to conduct additional microbiological testing. FDA notes that, if such additional testing is conducted, the Agency expects that the manufacturer would monitor such testing and act appropriately on the results.

(Comment 115) Some comments stated that the proposed regulations encompass a HACCP-type approach but the requirement for routine end product testing for certain micro-organisms is contradictory to the HACCP concept. However, these comments suggested that if end-product testing is required, FDA should issue guidelines on the number and size of samples to be tested to ensure that lots (production aggregates) of powdered infant formula do not contain pathogens.

(Response) FDA disagrees with this comment. The purpose of this interim final rule is to establish CGMP for infant formula. Thus, the premise of the comment is erroneous.

Moreover, FDA does not agree that end-product testing is contradictory to the HACCP concept. Although the HACCP concept may emphasize process controls, finished product testing at the final product stage, before distribution, is an important means of verifying that process controls are being continuously applied and effective. As discussed in response to Comment 116, testing representative samples of final production aggregates can serve as a final check on both the food safety controls and process designed to prevent microbial contamination during processing and on the microbiological safety of the infant formula prior to distribution.

The Agency is not issuing guidance on a sampling plan for microbial testing, as requested in the comment, because the number and size of formula samples for testing from each production aggregate are specified in § 106.55(e) of the interim final rule. As discussed in section V.J.2.c., by specifying the number and size of the samples for testing finished product, FDA ensures that there is sufficient statistical confidence to support the validity of results showing that the finished product meets the specified microbiological standards.

(Comment 116) Some comments asserted that there is no need to establish a standard for *E. sakazakii* (*Cronobacter* spp.) because the safety of infant formula would be better assured by hazard analysis critical control plans (HACCP), environmental monitoring, labeling, and education.

(Response) FDA disagrees with these comments. In the 2006 reopening, FDA noted that comments in response to the 1996 proposal suggesting that alternatives to end-product testing would provide sufficient assurance of safety (*e.g.*, HACCP plans and environmental monitoring, labeling, and education on formula preparation and handling) had not submitted any data or other information to support such assertions with respect to *Cronobacter* spp. All of the approaches mentioned in these comments may contribute to a total food safety plan, but essential to the plan is verifying the effectiveness of the process control established to ensure the microbial safety of the finished food product. Testing final production aggregates for *Cronobacter* spp. is one way that the manufacturer can verify the production process and the safety of the product prior to distribution and marketing. Further, FDA did not receive any information or data in response to the 2006 reopening that contradicts its tentative conclusion regarding microbiological testing of powdered infant formula for *Cronobacter* spp.

ii. *Microbiological specifications and powdered infant formula.*

(Comment 117) One comment questioned the practicality of including specific microbiological specifications in the CGMP given the length of time required to pass or change such regulations. The comment suggested that, in the future, when FDA encounters emerging pathogens of concern, it could establish interim requirements through such mechanism as a guidance document, which would be less burdensome than establishing the CGMP regulations.

(Response) FDA disagrees with the comment to the extent that it suggests that the Agency issue guidance instead of establishing standards for microbiological contamination for any future emerging pathogens of concern. In many cases, guidance is not a long-term substitute for a binding regulation. FDA's Good Guidance Practices (GGPs) (21 CFR 10.115) state that guidance represents the Agency's current thinking on a topic and does not create or confer any rights for or on any person and does not operate to bind FDA or, more importantly in this case, the public, including infant formula manufacturers. As discussed in response to Comment 116, the population for whom infant formula is manufactured and the risks for that population from microbial contamination require that FDA establish legally binding requirements. Because the process for issuing guidance is somewhat simpler than the process for promulgating a regulation, the Agency acknowledges that it may be appropriate, in some circumstances, to use guidance to communicate FDA's current thinking on specifications for an emerging pathogen of concern.

(Comment 118) One comment asserted that although manufacturers can take proactive measures to reduce the level, frequency, and incidence of *E. sakazakii* (*Cronobacter* spp.) in powdered infant formula, total eradication of the microorganism from powdered infant formula is not currently technologically possible given the nature of food powder manufacturing. The comment stated that manufacturers are currently attempting to further define and reduce, to the extent possible, any potential risk posed by contaminated powdered infant formula.

(Response) Even if the total eradication of *Cronobacter* spp. may not be technologically feasible, that limitation does not alter the Agency's conclusion that a strict microbiological standard, such as that required by the interim final rule (less than one organism in 300 grams of powdered formula) is necessary to reduce the risk of illness associated with *Cronobacter* spp. in infants. Powdered infant formula cannot undergo a post-packaging thermal process that is required for liquid ready-to-feed or concentrated

products. This fact supports the need for a microbiological standard for powder formula to ensure that the safest product possible is available to infants. Under § 106.6(b) of the interim final rule, a manufacturer must take responsibility to establish appropriate controls and monitor those manufacturing processes where adulteration could occur, and § 106.55(a) of the interim final rule requires a manufacturer specifically to establish a system of process and controls to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

b. *Need for a Cronobacter spp. (E. sakazakii) microbiological standard for powdered infant formula.*

i. *Need for a standard for formula for term infants.*

(Comment 119) One comment asserted that, given infant formula's excellent safety record since the passage of the Infant Formula Act, there is no need for additional microbiological requirements.

(Response) FDA disagrees with this comment. *Cronobacter* spp. have been documented as responsible for infant illnesses such as bacteremia, sepsis, and meningitis, with a reported mortality rate as high as 40 to 80 percent (Ref. 33). These cases of *Cronobacter* spp. infections have been associated both directly with powdered infant formula and epidemiologically (Refs. 33, 34, and 35). The existence of outbreaks associated with powdered infant formula contaminated with *Cronobacter* spp., such as the one that occurred in Tennessee (Ref. 34), attests to the ability of this pathogen to cause significant illness and death. Accordingly, the safety record for infant formula does not obviate the need for the microbiological requirements of this interim final rule.

(Comment 120) Several comments noted that there are data demonstrating that the industry has taken measures to achieve increased control over potential contamination of powdered infant formula overall and that since July 2003, there has been a reduction in the level of *E. sakazakii* (*Cronobacter* spp.) found in powdered infant formula.

(Response) FDA agrees that available data appear to suggest that the risk of *Cronobacter* spp. contamination of powdered infant formula has decreased. One of the earliest surveys of powdered infant formula samples for *Cronobacter* spp. was conducted in 1988 by Muytjens and co-workers (Ref. 36). The investigators reported that 14 percent of samples of powdered infant formula that had been collected from 13 countries contained the pathogen at levels that ranged from 0.36 to 66 CFU/100 g. A more recent analysis of 82 powdered infant formulas by Iversen and Forsythe (2004) documented *Cronobacter* spp. in approximately 2.4 percent of samples (Ref. 37). Although these two investigations appear to reflect a reduction in the percent of formula contaminated with *Cronobacter* spp., the risk of potentially fatal illness will persist as long as the pathogen can survive in the environment and in powdered formula. To the extent the comment is suggesting that there is no need to establish a standard for this organism given the reduction in the percent of formula contaminated with *Cronobacter* spp., the Agency disagrees. Given the severe consequences of a *Cronobacter* spp. infection in an infant, protection of the public health requires that the Agency establish a standard for this organism in powdered infant formula and require sampling and testing to achieve that standard.

(Comment 121) One comment asserted that there have been no reported cases linking powdered infant formula to illness caused by *E. sakazakii* (*Cronobacter* spp.) in healthy term infants except when there was positive evidence of external contamination or abuse of reconstituted formula. Another comment argued that, based on the lack of evidence linking *Cronobacter* spp. to outbreaks in term infants, FDA's current *de facto* standard of zero tolerance of *Cronobacter* spp. in term infant formulas is not warranted.

(Response) FDA disagrees with these comments because the available scientific evidence demonstrates that term infants are at risk of foodborne illness associated with powdered infant formula contaminated with *Cronobacter* spp., including the risk of severe morbidity and mortality. FDA notes that powdered infant formula is not intended to be, nor is it, a sterile product. Because term infants are more likely to receive powdered formula rather than liquid formula that is commercially sterile, they risk being exposed to *Cronobacter* spp.

Reports in the published literature document the existence of this risk for term infants. For example, in 1989, Biering *et al.* reported three cases of neonatal meningitis associated with *Cronobacter* spp. in three infants fed powdered milk formula where two of the three infants were term infants (Ref. 38). The *Cronobacter* spp. isolated from the term neonates was indistinguishable from the 22 strains grown from the powdered infant formula. Muytjens *et al.* (1983) reported on one term infant infected with *Cronobacter* spp. infection who died from bacteremia (Ref. 39).

Additionally, FDA and CDC have both received reports through the agencies' electronic adverse event reporting systems or otherwise of several cases of healthy term infants becoming ill from *Cronobacter* spp. infection (Ref. 40). In each case, contaminated powdered infant formula was the suspect vehicle. Although followup investigations of these cases were unable to determine the source of contamination that caused the illness, these reports demonstrate nonetheless that healthy term infants continue to be at risk of life-threatening illness from *Cronobacter* spp. infections. Importantly, illnesses from Cronobacter spp. are not required to be reported to the CDC (Ref. 41). Detection of the pathogen and the disorders has been identified through surveillance surveys. This suggests that the actual number of cases of *Cronobacter* spp. infection in infants is under-reported.

Although infant age is not protective, infant age may be associated with particular presentations of *Cronobacter* spp. illness. That is, CDC data suggest that infants who develop meningitis tend to be near term in gestational age and birth weight (Ref. 33). Consistent with this observation are conclusions from the FAO/WHO expert consultation that identified the two risk groups as "preterm infants who develop bacteraemia outside of the neonatal period, with most, but not all, cases occurring in infants under two months, and term infants who develop meningitis during the neonatal period." (Ref. 3) Importantly, the FAO/WHO report further notes that "any infant may develop either syndrome at any age."

FDA also notes that the comment incorrectly asserted that the *Cronobacter* spp. standard is a zero tolerance standard. In fact, this is not the case, as explained in the discussion of the standard and the sampling plan (section V.J.2.c).

(Comment 122) One comment argued that the low risk among healthy term infants is supported by the low number of reported cases among healthy term infants in comparison with the estimated 100,000 infants who have been exposed to contaminated formula in the past 15 years.

(Response) FDA agrees that the number of reported cases of illness in term infants with *Cronobacter* spp. infection is less than those of preterm infants but notes that the comment does not dispute the Agency's conclusion that term infants have been afflicted with serious illness caused by *Cronobacter* spp. infections. Term infants have been reported ill from contaminated powdered infant formula

(Refs. 35 and 38), and several cases of term infants seriously affected by *Cronobacter* spp. infections, without a clear association to powdered infant formula, have been reported to FDA and CDC (Refs. 40 and 41). As described in the response to Comment 112, extremely serious health conditions, such as meningitis, bacteremia, seizures, brain abscess, hydrocephalus, developmental delay, and death associated with infection from *Cronobacter* spp. have been reported in the scientific literature (Refs. 33 and 42) and directly to FDA or the CDC (Ref. 40). Thus, in light of the consequences of an infection from *Cronobacter* spp., even a "low risk" of such infection in healthy infants is unacceptable and is appropriately compared to what is essentially a zero risk of a *Cronobacter* spp. infection in breast-fed infants.

(Comment 123) One comment suggested that products clearly labeled for infants six months of age or older should be exempt from the *E. sakazakii* (*Cronobacter* spp.) microbiological standard because there is no evidence powered infant formula has caused any cases of *E. sakazakii* (*Cronobacter* spp.) infection in older infants.

(Response) FDA disagrees with this comment for several reasons. First, although *Cronobacter* spp. infections are less frequently reported in infants six months of age and older than in younger infants, older infants are nevertheless at risk of *Cronobacter* spp. infections and the scientific literature includes reports of such infections in older infants. In 2003, a case of *Cronobacter* spp. infection in a healthy eight month old infant was reported directly to the FDA and CDC (Ref. 40). The patient was healthy prior to consuming powdered infant formula a few hours before the onset of symptoms of illness. Likewise, in its expert review of multi-country data on the risk of illness from *Cronobacter* spp., FAO/WHO reported that of 120 individually documented cases among infants and young children up to 3 years of age, six occurred in infants aged 6 to 11 months and two cases in children 12 to 36 months (Ref. 43). Importantly, the FAO/WHO report also noted that there are few data available on the prevalence of the *Cronobacter* spp. pathogen in formulas specifically intended for infants ages 6 to 11 months (so-called "follow-up formula"), a situation attributed to the absence of mandatory testing for *Cronobacter* spp. (Ref. 43).

Second, a food that is capable of causing severe illness is adulterated within the meaning of section 402(a)(1) of the FD&C Act because the presence of a microorganism, and labeling to restrict the food's use to certain subpopulations cannot make that unlawful food lawful.

Third, section 201(z) of the FD&C Act defines "infant formula" as "a food that purports to be or is represented for special dietary use solely as a food for infants." FDA's regulations (21 CFR 105.3(3)) define "infant" as a person not more than 12 months of age. Accordingly, the U.S. regulatory system does not distinguish between formula for infants less than 6 months of age and formula intended for infants older than 6 months. (The latter is often referred to as "followup" formula.) Thus, all infant formula for infants ages 0 to 12 months must meet the same microbiological standards and requirements under this interim final rule.

For these reasons, FDA declines to adopt the suggestion of this comment.

(Comment 124) One comment asserted that formula labeled for infants 6 months of age and older should be exempt from the *E. sakazakii* (*Cronobacter* spp.) standard. The comment noted that in 2003, the FAC defined the at-risk population as preterm infants born at less than 36 weeks gestational age up to a post term age of 4–6 weeks, immunocompromised infants at any age, and term infants. The comment asserted that the FAC did not identify healthy-term infants as at risk.

(Response) FDA does not disagree that preterm and immunocompromised infants are at greater risk of infection from *Cronobacter* spp. compared to term infants and infants six months of age and older. However, as demonstrated by the evidence discussed in the previous responses, term infants are still at risk of infection from *Cronobacter* spp.; these infections are very serious and can lead to life-long disability or death. The FAO/WHO 2008 report on the risk of illness from this pathogen in powdered follow-up formula made several significant observations: (1) Six cases of illness from *Cronobacter* spp. were identified in infants between the ages of 6 and 11 months; (2) globally, there are few surveillance data for *Cronobacter* spp. related illness; (3) because there is no universal mandate for testing followup formula for this pathogen, there are few data available on the prevalence of the pathogen in these products intended for older infants; and (4) there are data to demonstrate that followup formula is consumed by infants less than 6 months of age and sometimes consumed by infants less than 1 month (Ref. 43). To exempt followup formula from the CGMP microbiological standards in this interim final rule would be to ignore the very real potential for serious illness in this older group of infants consuming these formulas, as well as infants less than six months of age that may be consuming these formulas.

Accordingly, FDA declines to exempt "follow-up formula" from the interim final rule's standard for *Cronobacter* spp.

(Comment 125) One comment asserted that although the available scientific evidence does not permit a comprehensive risk assessment, the available evidence does permit the rather straightforward conclusion, such as that reached by the Food Advisory Committee, that whatever the risk powdered infant formula may pose to term infants by virtue of the presence of *Cronobacter* spp., that risk is not only lower than that which is associated with premature infants, but also is unquantifiable.

(Response) FDA disagrees in part and agrees in part with this comment. Importantly, as discussed in detail in this document, a scientifically sound quantitative risk assessment can be, and has been, conducted of the potential for *Cronobacter* spp. infection in infants. As noted in its response to Comment 114, FDA does agree that the incidence of illness from *Cronobacter* spp. infection is lower in term infants than in premature infants. Nonetheless, as also explained previously in this document, it is appropriate to establish a *Cronobacter* spp. standard for all infant formula, including formula for older infants. Accordingly, FDA is not revising § 106.55 in response to this comment.

ii. *Issues related to the standards for Cronobacter spp.*

(Comment 126) One comment, which questioned the proposed standard, stated that a research study by Health Canada, in which a suckling mouse was used as a model to study *E. sakazakii,* found that this organism has low infectivity, and that large numbers of organisms are needed to cause infection, even with the most virulent strains.

(Response) As discussed in this document, this study does not demonstrate that the *Cronobacter* spp. organism has low infectivity.

The research by Health Canada identified in the comment was designed to study virulence factors and pathogenesis of *E. sakazakii* (*Cronobacter*) using the suckling mouse assay (Ref. 44). The animals were challenged both by oral and intraperitoneal routes with clinical and food isolates of the pathogen. The investigators reported that one strain of the pathogen (MNW2), which was administered orally, was lethal to suckling mice at 10^8 CFU per mouse,

while others were lethal at doses greater than 10^8 CFU per mouse. In a more recent animal study, Richardson *et al.* (2009) evaluated the infectivity and lethality of the MNW2 strain of *Cronobacter* spp. in three different strains of neonatal mice to determine whether neonatal mice could be used as a model for *Cronobacter* spp. infection in premature infants (Ref. 45). The investigators found that one of the three mouse strains was the most susceptible to the pathogen and had the lowest infectious dose (10^2 CFU) and the lowest lethal dose (10^2 CFU) (Ref. 45). The investigators noted that there was not a clear dose-dependent response after treatment with the pathogen.

FDA finds that the contradictory results of these two studies demonstrate that more research is needed to identify an appropriate animal model, or specific strain of animal, for *Cronobacter* spp. research. Neither study clearly established the relationship between growth of the pathogen in mice and growth of the pathogen in an infant. The results of these studies do show that *Cronobacter* spp. is an infectious and lethal pathogen. As noted, this organism has a 40–80 percent lethality in infant illness (Ref. 45).

(Comment 127) One comment argued that infections are primarily associated with foods in which the pathogen has significantly multiplied, but there is scant to no evidence to suggest that ingestion of small numbers (<100 CFU) of *E. sakazakii* (*Cronobacter* spp.) or *Listeria monocytogenes* causes illness in high risk populations. The comment added that because of the presence of both pathogens in the environment, there is the potential for contamination of foods during at-point-of-use preparation as well as the potential for growth during subsequent storage. Thus, the comment asserted that high-risk processed foods initially free of the pathogens can become contaminated and abused by the food preparer resulting in a dangerously unsafe product. The comment stated that establishing a zero tolerance for these pathogens in high-risk foods will not address the issue.

(Response) As discussed in section V.J.2.e, FDA has determined that the interim final rule will not include a standard for *Listeria monocytogenes*. Thus, the Agency's response to this comment addresses the issues in the comment only from the perspective of *Cronobacter* spp.

FDA disagrees with this comment for several reasons. First, the Agency is aware that the available data are not adequate to identify with certainty the infectious dose for *Cronobacter* spp. Importantly, however, FDA disagrees that the absence of information on the infectious dose supports the conclusion that these organisms pose little or no risk of illness in high risk populations when ingested in small numbers.

Second, the available evidence demonstrates that post-processing contamination is not required for there to be an illness outbreak as illustrated by the investigation of the 2001 Tennessee outbreak of *Cronobacter* spp. infection. As part of the follow-up investigation, hospital personnel reviewed Neonatal Intensive Care Unit (NICU) infection-control practices, policies, and procedures for preparation, storage, and administration of powdered infant formula (Ref. 34), and no breaches in infection control were identified. The investigation determined that the formula was prepared in the NICU according to manufacturer's instructions and that the powdered formula was mixed with sterile water, immediately refrigerated, and used within 24 hours of preparation. The infant that developed *Cronobacter* spp. meningitis was given formula by continuous administration; administration or "hang" time (i.e., the amount of time the contents of a formula bag are fed to a patient) did not exceed 8 hours. A second outbreak in a Belgian hospital NICU also documented that infections associated with powdered infant formula may occur in high-risk infants despite proper formula preparation. In this instance, formula powder that was apparently contaminated was prepared and administered according to NICU protocol, and resulted in serious illnesses (including two deaths) of 12 premature infants (Ref. 46).

Finally, although there is potential for contamination of foods during preparation and subsequent storage, that fact does not negate the need to establish a tolerance. FDA disagrees that establishing a tolerance (claimed by the comment to be a zero tolerance) for these pathogens in high-risk foods will not address the illness issue. One purpose of the CGMPs in this interim final rule is to focus on manufacturing controls to help eliminate the potential for microbial contamination of formula during processing and thus reduce the risk of potential illness from powdered infant formula contaminated, even at low levels, with harmful microorganisms. The Agency also disagrees that the microbial standard for *Cronobacter* spp. established in § 106.55 of the interim final rule is a "zero tolerance" standard, and we respond to this comment in section V.J.2.c.

iii. *Issues related to alternatives to testing for Cronobacter spp.*

(Comment 128) One comment suggested that the addition of *E. sakazakii* (*Cronobacter* spp.) inhibitors to formula, such as antimicrobials inhibitory to *E. sakazakii* (*Cronobacter* spp.) that are presently approved for use in foods, provide a more effective means of preventing the growth of *E. sakazakii* (*Cronobacter* spp.) that may occur under conditions of abuse. Importantly, however, the comment stated that use of such antimicrobials would require that the formula not have an initial level of contamination that would be considered unsafe.

(Response) FDA disagrees with the suggestion of this comment for two reasons. First, the use of antimicrobials was not suggested as an alternative to finished product testing. Rather, the comment proposed that such inhibitors be used to manage the risk of post-rehydration abuse. Thus, the comment does not provide a basis for rejecting the Agency's tentative conclusion that testing finished powdered infant formula is necessary to control contamination from *Cronobacter* spp. before rehydration. Second, as noted in the 2006 reopening, the comment suggesting the use of inhibitors to *Cronobacter* spp. in powdered formula did not provide data to demonstrate the effectiveness of such ingredients to control this pathogen in a powdered infant formula matrix. For these reasons, FDA concludes that the use of antimicrobials is not an alternative to establishing a standard for *Cronobacter* in finished infant formula products.

(Comment 129) Several comments suggested that instead of requiring testing for *E. sakazakii* (*Cronobacter* spp.), FDA should instead require stricter testing for indicator organisms, such as *Enterobacteriaceae* (which include *E. sakazakii* (*Cronobacter* spp.)). A second comment recommended testing for the presence or absence of *Enterobacteriaceae*, rather than requiring a quantitative analysis. The second comment further suggested that a standard for *Enterobacteriaceae* of zero organisms in a ten gram sample would provide an appropriate level of assurance and that this criterion should be applied to all formulas, including exempt formulas.

(Response) FDA disagrees with the comments that support testing powdered infant formula for the presence or absence of an indicator organism, specifically *Enterobacteriaceae*, as an alternative to testing directly for *Cronobacter* spp. The Agency also notes that this interim final rule does not extend to exempt infant

formulas. Thus, this response does not address the comment regarding the appropriateness of testing exempt formula.

Cronobacter spp. is a member of the *Enterobacteriaceae* family. Detection and identification of the organism have presented methodological difficulties, which difficulties were considered when determining the finished product standard. Baumgartner *et al.*, (2009) reported that some methods for the detection of *Enterobacteriaceae* may not effectively identify or otherwise be used to determine the presence of *Cronobacter* spp. (Ref. 47). The standard methods of isolation for *Enterobacteriaceae* are not specific for *Cronobacter* spp., and detection of the *Cronobacter* organism is further complicated by the sensitivity of a number of *Cronobacter* spp. strains to certain chemicals used in isolation and detection media for *Enterobacteriaceae* (Refs. 37, 48, and 49). Studies have shown that specially modified enrichment media are needed for the detection of this pathogen (Refs. 48, 50, and 51) and are described on the FDA Web site (*http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114665.htm*). In addition, the primary microbial populations found in powdered infant formula are *Bacillus* species and other gram-positive bacteria, which bacteria may have an adverse affect on the enrichment and isolation of *Enterobacteriaceae* (Ref. 52).

Detection, identification, and specificity of *Cronobacter* spp. are critical to effective management of this pathogen. *Enterobacteriaceae* may not function effectively as in indicator of the presence of *Cronobacter* spp. because testing for *Enterobacteriaceae* may produce a negative result for *Enterobacteriaceae* even though *Cronobacter* spp. is present. Because powdered infant formula is not a sterile product, any post-heat treatment contamination with *Cronobacter* spp. may be from a source where *Enterobacteriaceae* are not present but *Cronobacter* are. These same observations and conclusions were reported by Paoli and Hartnett (2006) in their article "Overview of a risk assessment model for *Enterobacter sakazakii* in powdered infant formula" (Ref. 53). Following a statistical evaluation of the relationship between *Enterobacteriaceae* and *Cronobacter* spp., the investigators concluded the data indicated that a strong positive relationship between the concentrations of the pathogens could not be inferred and that the absence of *Enterobacteriaceae* in a powdered infant formula sample did not necessarily mean that *Cronobacter* spp. were not present. Thus, relying on testing for *Enterobacteriaceae* to identify *Cronobacter* spp. could produce a false negative finding, resulting in the release of product for distribution that is contaminated with *Cronobacter* spp.

For these reasons, FDA declines to require the use of *Enterobacteriaceae* as an indicator organism to identify the presence of *Cronobacter* spp. in powdered infant formula as an alternative to a specific standard for *Cronobacter* spp. The interim final rule's standard for *Cronobacter* spp. is discussed in detail in section V.J.2.c.

iv. *The microbial risk assessment.*

(Comment 130) One comment requested that FDA make available to the public a risk assessment or risk profile analysis to support its *Cronobacter* spp. standard.

(Response) The comment requesting public disclosure of a risk assessment or risk profile analysis was submitted prior to several important actions related to microbial contamination of powdered infant formula. These subsequent activities have effectively responded to the comment's request.

In particular, as discussed previously in this document, FAO/WHO organized two expert consultations (2004 and 2006) on *Cronobacter* spp. contamination of powdered infant formula. The second consultation culminated in the 2006 FAO/WHO report, *Enterobacter sakazakii* and Salmonella in Powdered Infant Formula, which report included a quantitative risk assessment of *Cronobacter* spp. contamination of such formula (Ref. 3). In the 2006 reopening, FDA summarized the FAO/WHO risk assessment model and announced the Agency's tentative decision to rely on that assessment to support the Agency's risk management decision as reflected in the proposed *Cronobacter* spp. standard. At the time of the 2006 reopening, a pre-publication copy of the 2006 FAO/WHO report was made available for review at FDA's Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 (Ref. 3). The final FAO/WHO report is also available at FDA's Division of Dockets Management and also at the following Web site: *http://www.who.int/foodsafety/publications/micro/mra10.pdf.* FDA notes that another document providing additional insight into the 2006 risk assessment is "Overview of a Risk Assessment Model for *Enterobacter sakazakii* in Powdered Infant Formula" (Ref. 53). This document is likewise available at the Division of Dockets Management and on the FAO/WHO Web site at *www.who.int/foodsafety/micro/jemra/r_a_overview.pdf.*

The Agency's review of the data and quantitative risk assessment model as applied to *Cronobacter* spp. led to its tentative conclusions to establish a standard for this pathogen. Since the 2006 reopening, there have been no further scientific data made available to cause the Agency to change its tentative conclusions.

Accordingly, FDA has responded to this comment.

(Comment 131) One comment expressed concern that the risk assessment model relied upon by the Agency to propose a standard for *E. sakazakii* (*Cronobacter* spp.) lacks sufficient supporting evidence, particularly dose-response data.

(Response) FDA disagrees with this comment for several reasons.

First, one reason that quantitative risk assessment methodology has been developed is to allow assessment of risk even where data are limited; such methodology generally anticipates further refinements as more data become available. The FAO/WHO Guidelines on "Exposure assessment of microbiological hazards in foods" (Ref. 54) discuss the characteristics of data used in an exposure assessment and note that the iterative nature of an exposure assessment is "concerned with the fact that initial attempts to model a process are likely to utilize data with a high degree of uncertainty. This process can be used to identify where the greatest uncertainty lies, allowing targeted data collection for subsequent model updating" (Ref. 54).

Second, the Agency acknowledges that there are no complete dose-response data for infants who consumed powdered infant formula and developed *Cronobacter* infections. Similarly, as discussed previously in this document, there are as well insufficient data in animals to characterize a dose-response relationship. It is unlikely that sufficient empirical data in infants will be developed even to establish an infectious dose, i.e., the lowest dose of the pathogen required to cause illness, for *Cronobacter,* because the illness is relatively rare and such research would present significant ethical problems. If and when an appropriate animal model is identified, more research can perhaps be done to try to develop data on an infectious dose and a dose-response curve in order to gain a better understanding of the infectivity of *Cronobacter* spp. in infants.

Even in the face of limited data (Refs. 33, 34, and 46), the severity of the public health risk from *Cronobacter* spp.

infections requires action by FDA. In this instance, the available tool is a risk assessment grounded in well-considered, conservative estimates; as more data become available and are applied to the model, the levels of uncertainty will be reduced. Although the FAO/WHO risk assessment was based on several estimates, the expert committee was fortunate to receive data on the initial levels of *Cronobacter* spp. contamination of infant formula from formula manufacturers worldwide. It is also important to note that the technical experts at the 2006 FAO/WHO meeting in Rome, including representatives from FDA and CDC, reviewed and endorsed the risk assessment, finding it to be "accurate and valid, based on the approach taken, the assumptions made and the interpretation of data" (Ref. 2, p. xvi) (see *http://www.who.int/foodsafety/publications/micro/mra10.pdf*).

For these reasons, FDA concludes that the FAO/WHO risk assessment model is sound and an extremely valuable tool for managing the risk presented by *Cronobacter* contamination of infant formula in the United States.

(Comment 132) One comment asserted that there is no "nominated dose-response" used to support the arguments, that a risk model is a measure of relative rather than actual risk, and that caution is needed when determining criteria to use to support a standard.

(Response) It is not clear what this comment means by "nominated dose-response." In the absence of an appropriate animal model, it is not possible to establish a level of *Cronobacter* spp. in powdered infant formula that, when consumed by infants, will result in illness. It is reasonable, therefore, for FDA to employ a well-considered, conservative estimate of the probable level of pathogen required to cause illness.

In the absence of specific dose-response information, the exposure assessment model used by the FAO/WHO expert group assumed that one colony-forming unit of *Cronobacter* spp. per gram (1 CFU/g) powdered infant formula was capable of causing illness (Ref. 53). In the application of the model, this level was adjusted to take into account any growth or decline that may occur due to the conditions of use.

The hazard characterization portion of the 2006 FAO/WHO risk assessment model was used to evaluate the probability that illness would result from powdered infant formula contaminated with *Cronobacter* spp.; this probability of illness was assessed using an exponential dose-response model in which an initial contamination level of 1 CFU/g of *Cronobacter* spp. was assumed to cause illness (Ref. 53). The risk assessors explained that this initial level of 1 CFU/g per serving was "adjusted to take into account any growth or decline that may occur due to the conditions of preparation, holding and feeding to give an estimate of the dose ingested" (Ref. 53). Because there were no data available at the time of the risk assessment to estimate the value of the model's dose-response parameter, six options were presented to represent the baseline dose-response parameter. It was assumed that the dose-response parameter would likely be specific for each of the infant groups considered in the model. The risk assessment used a value of 1 for the dose-response multiplier, which enables a direct comparison of the impact of the assumptions regarding the value of the dose-response parameter and the relative susceptibility of the infant groups in terms of the estimates of risk (Ref. 53).

For these reasons, the absence of an empirical dose-response does not preclude managing the risk presented by *Cronobacter* ssp. in powdered infant formula by relying on the FAO/WHO quantitative risk assessment.

(Comment 133) One comment argued that the risk assessment used an incorrect premise that healthy newborns should be grouped with premature infants.

(Response) FDA disagrees with this comment. The risk assessment appropriately grouped together healthy terms infants and preterm infants. The report of the 2006 risk assessment explains this approach, which FDA endorses. Specifically, the expert consultants reviewed the available outbreak data and noted that the cases could be grouped into two risk groups in terms of age at which the illness occurred: "premature infants who developed bacteraemia outside of the neonatal period, with more, but not all, cases occurring in infants under 2 months; and term infants who develop meningitis during the neonatal period." *http://www.who.int/foodsafety/publications/micro/mra10.pdf*, (Ref. 54, p. 14). These experts further observed, however, that the differences in timing of infection onset may have been related to differences in timing of exposure to the pathogen rather than to differences in susceptibility. They concluded that any infant may develop either syndrome (i.e., bacteraemia or meningitis) at any age (Ref. 54, p. 14).

FDA agrees with the FAO/WHO expert consultants that the outbreak data support the observation that both preterm and term infants are at risk of illness from consuming powdered infant formula contaminated with *Cronobacter* spp. and that the impact of illness from this pathogen is significant for the term infant and the premature infant alike. Because both premature and term infants are susceptible, at different times in their lives, to illness from this pathogen and may be fed powdered formula, it was reasonable and appropriate for the two cohorts to be grouped together in the risk assessment.

c. *Microbiological standards for powdered infant formula for Cronobacter spp. and Salmonella spp.*

In the 2006 reopening, FDA tentatively concluded that it was appropriate to establish a standard for *E. sakazakii* (*Cronobacter* spp.) of negative in 30 × 10 g samples (71 FR 43392 at 43395). The Agency suggested no change to the proposed standard for *Salmonella* spp. of negative in 60 × 25 g samples.

i. *The sampling plan—Cronobacter spp.*

(Comment 134) Several comments agreed with the need to establish a microbiological standard for *E. sakazakii* (*Cronobacter* spp.), but did not suggest a specific standard. Several other comments agreed with FDA regarding the proposed microbiological standard and the proposed sampling plan for *Cronobacter* spp. (negative in 30 × 10 g samples.) Other comments requested that FDA provide an explanation of the number and sample sizes required to test finished formula product for contamination.

(Response) To place in context FDA's tentative decision to establish a standard of negative in 30 × 10 g samples for *Cronobacter,* it is useful to understand the outlines of the risk assessment and risk management processes both generally and specifically with respect to *Cronobacter* contamination of powdered infant formula.

Risk assessment and risk management are two separate, though related, parts of the process to address a hazard. At the risk assessment stage, the nature and probability of an adverse event is calculated. Often, this calculation is an estimate based on a less than complete set of empirical data. At the risk management stage, the risk manager determines the tolerable level of risk (or the level of protection) and the desirable level of confidence that the level of protection will be achieved.

In the case of *Cronobacter* contamination of powdered infant formula, a quantitative risk assessment model was developed as part of the FAO/WHO expert consultation (Ref. 3).

This model estimates the risk of *Cronobacter* illness to infants consuming powdered infant formula and "provides the means to evaluate microbiological criteria and sampling plans in terms of the risk reductions achieved and the percentage of product [production aggregates] rejected." (Ref. 3, p. xii). All told, the model was used to project risk reduction and product rejection rates for 162 different scenarios (Ref. 3, pp. 46–47). Importantly, the FAO/WHO expert group did not select a specific approach to managing the *Cronobacter* hazard; instead, the 2006 Rome Report recommended that each country manage this risk using the risk assessment model (Ref. 3, p. xiv–xv).

Accordingly, using the information from and applying the FAO/WHO risk assessment model, FDA subsequently engaged in the risk management phase of addressing the *Cronobacter* hazard. Specifically, the Agency identified both the appropriate level of protection (*i.e.,* the level of contamination below which we would not expect in a *Cronobacter* infection to occur) and the level of desired certainty that such level of protection would be achieved (i.e., the confidence level). In making these determinations, FDA sought to balance the risk of illness and the likely percentage of production aggregates of formula that would be rejected due to a finding of the presence of *Cronobacter* spp., and tentatively determined that a sampling plan of 30 samples of 10 g each per production aggregate would appropriately manage the risk of *Cronobacter* infections from powdered infant formula. According to the FAO/WHO risk assessment model, the 30 × 10 g sampling plan (that is, negative for *Cronobacter* in 30 × 10 g or 300 g total) would result in approximately 20 percent fewer cases of *Cronobacter* illness each year and the rejection of 1.4 percent of production aggregates of powdered infant formula.

(Comment 135) One comment stated that FDA's regulatory sample size of 30 × 10 g samples would not provide a high level of assurance that the lot (production aggregate) was not contaminated because unlike chemicals which may be uniformly dispersed throughout a powdered formula, bacteriological contamination is likely to be unevenly distributed in the final lot (production aggregate). The comment asserted that because microbiological contamination present in finished powdered infant formulations produced in inadequately controlled systems are likely to be uneven and at low levels, sample size would have to reach excessive levels (at a minimum ten percent of the lot (production aggregate)) to ensure meaningful results.

(Response) FDA disagrees with this comment. The Agency notes that the comment did not provide any data to support its assertion that, to ensure meaningful results, the proposed sample size would have to reach a minimum of 10 percent of the production aggregate. FDA agrees that microbiological contamination of powdered infant formula may be unevenly dispersed in the production aggregate, particularly when there is low level contamination. However, even where the pathogen is unevenly dispersed, an appropriately designed and executed sampling plan can help to address the variability and uncertainty created by such conditions. In addition to establishing a limit for the pathogens of concern, microbiological criteria include the testing method employed, the sampling plan (size and number of samples to be examined), and the actions to be taken when the microbiological limits are exceeded (Ref. 54, p. 62).

The sampling plan for *Cronobacter* spp. is intended to help manufacturers identify unacceptable production aggregates at the finished product stage, *i.e.,* those production aggregates not complying with the established limits, before release for distribution. To establish an appropriate sampling plan, it is necessary to consider, for any production aggregate, the likely level of contamination and the variability within the production aggregate in order to evaluate the likelihood that a sample will be positive for the pathogen (Ref. 55). Because there will be variability between and among production aggregates, the true concentration of the pathogen in a production aggregate cannot be determined with 100 percent accuracy. Thus, the average of the concentrations of the pathogen across all production aggregates and the "between production aggregate variability" among production aggregates is used to determine the percentage of production aggregates likely to be rejected by a particular sampling plan. This statistical approach is commonly used to establish microbiological and chemical contaminant sampling plans for regulatory purposes.

With any sampling plan in which there is variability in the concentration and dispersion of the contaminant, there is the likelihood that some "good" production aggregates may be rejected by the sampling plan (false positives) and that some "bad" production aggregates (false negatives) may be deemed acceptable. In a public health environment, FDA is most concerned about the risk to infants by the acceptance of false negative ("bad") production aggregates by the sampling plan.

As noted previously in this document in response to Comment 134, the FAO/WHO risk utilized a large body of data on the initial levels of *Cronobacter* spp. contamination of infant formula from formula manufacturers worldwide. Relying on these data, the proposed sampling plan for *Cronobacter* spp. of 30 × 10 g samples took into consideration the low levels of contamination and variability of contamination between and among production aggregates. The statistical design of the proposed sampling plan seeks to minimize false positives and false negatives and to maximize true findings of positive and negative, within a 95 percent confidence interval. As discussed in the 2006 reopening, based on the FAO/WHO risk assessment, the 30 × 10 g sample plan is expected to provide a relative annual risk reduction of 20 percent fewer cases (assuming a mean $\log_{10}$ concentration of pathogen of −5 CFU/g) and 37 percent (assuming a mean $\log_{10}$ concentration of −3 CFU/g) of illness from *Cronobacter* spp. than would be the case if there were no powdered infant formula sampling plan in place (71 FR 43392 at 43394–43395). Thus, the greater the contamination of the powdered infant formula, the greater the sampling can reduce the risk of illness, because as the level of contamination increases, the rejection rate of production aggregates increases and the relative risk reduction increases. If manufacturers focus on ensuring that the overall mean log concentration of the pathogen is low and that variation between lots (production aggregates) is controlled, the potential for rejection of the lot (production aggregate), and the risk of illness, are both reduced (71 FR 43392 at 43395).

(Comment 136) One comment argued that based on a lack of evidence linking *Cronobacter* spp. to outbreaks in term infants, FDA's *de facto* standard of zero tolerance for this pathogen in term infants is not warranted. Another comment contended that because high risk foods initially free of *E. sakazakii* (*Cronobacter* spp.) can become contaminated and abused by the food preparer resulting in a dangerously unsafe product, establishing a zero tolerance for the pathogen in high risk foods will not address the issue.

(Response) FDA notes that the Agency's response to the comment about term infants is addressed in Comment 121 (section V.J.2.b.i) and the comment regarding post-processing

contamination is addressed in Comment 127 (section V.J.2.b.ii).

For two reasons, FDA disagrees with the comment that the standard for *Cronobacter* spp. is zero. First, the sampling plan for *Cronobacter* spp. proposed in the 2006 reopening and established in this interim final rule is not zero; rather it is negative in a composite sample of 300 g (30 × 10 g samples) taken from a single production aggregate of finished product. In other words, the standard is the absence of the organism in a defined volume of powdered infant formula sampled from the production aggregate, which is not the same as the absence of the organism from the entirety of the production aggregate. This means that when the production aggregate is sampled and the composite is tested, if the pathogen is not detected, the manufacturer has a 95 percent level of confidence that there would be <1 CFU *Cronobacter* spp. in 100 g powder. The statistical validity of the sampling plan, based on an analysis of industry data, is discussed in detail in response to Comment 134 in this section. Not finding *Cronobacter* spp. analytically does not mean that the pathogen may not be present in the production aggregate; it could be present but at an extremely low level (<1 CFU/100 g). When the pathogen is present in the powdered formula, the sampling plan approach accounts for a widely dispersed and, typically, low level of contamination. For manufacturers who adhere to strict food safety controls during processing, the standard will have little impact on the number of production aggregates that would be rejected because of a positive finding for the organism.

Second, the limit of detection of FDA's *Cronobacter* spp. analytical method in the Agency's *Bacteriological Analytical Manual* (BAM) is 1 CFU/100 g (Ref. 56). This means that the lowest level of the pathogen that can be detected is 1 CFU; not zero.

For these reasons, FDA disagrees that the standard in § 106.55(e) of the interim final rule for *Cronobacter* spp. is a zero tolerance.

(Comment 137) One comment stated that it has been well documented in the literature that using small sample sizes of finished product will provide no assurance of product safety. The comment contended that, in the case of infant formula, to achieve ninety-nine percent assurance that the finished product does not contain a pathogen (*e.g., Salmonella* spp., *Listeria monocytogenes*) that is subject to a "zero" tolerance level, the manufacturer would have to randomly select hundreds of sample throughout the production aggregate, which would require significant financial resources.

(Response) FDA notes that in the 2006 reopening, the Agency tentatively decided to eliminate the proposed standard for *Listeria monocytogenes* (71 FR 43392 at 43396), and this interim final rule affirms that tentative decision. Thus, this response addresses the comment only to the extent that it concerns *Salmonella* spp.

The Agency disagrees that the proposed standard for *Salmonella* is zero tolerance for reasons that parallel those presented in response to comments regarding the standard for *Cronobacter* spp (see the response to Comment 135). In general, the sampling plan for *Salmonella* is based on the category of food in which it may be present. FDA's BAM describes three categories of foods (*http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm*). Of these, Category I Foods (defined as "foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption and are intended for consumption by the aged, the infirm, and infants") includes powdered infant formula. The current standard for Category I foods is negative in 60 x 25 g samples (*i.e.,* a total composite sample of 1500 g). When FDA tests a sample for the presence of *Salmonella* following the BAM method, four 375 g subsamples are removed from the 1500 g composite and tested for the pathogen as specified in the method. If no *Salmonella* are detected using the 60 X 25 g sampling, there is a 95 percent level of confidence that the pathogen, if present in the production aggregate, is < 1 CFU/500g of product. This sampling plan has been validated statistically and has been used to analyze many foods similar to powdered infant formula where the pathogen of interest is likely to be widely dispersed and at low concentration. This same sampling plan would provide the same level of confidence when used by a formula manufacturer to test final production aggregates. A finding of no *Salmonella* spp. in a 60 X 25 g composite of the manufacturer's powdered infant formula demonstrates, with 95 percent confidence, that the pathogen is present in the production aggregate at <1 CFU/500 g of product.

FDA notes that manufacturers may choose to do more intensive testing, such as testing using larger sample sizes or more samples, to enhance the confidence of the testing results. Further, the BAM analytical method for *Salmonella* has a limit of detection of 1 CFU/25 g and, for some products, 1 CFU/375 g; it cannot establish a total absence of the pathogen ("zero").

Based on the foregoing comments, § 106.55(b) of the interim final rule requires that manufacturers test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standard of negative in 30 x 10 g samples for *Cronobacter* spp. and negative in 60 x 25 g samples for *Salmonella* spp.

(Comment 138) One comment suggested that the level of 0.36 CFU/100 g should be considered safe for the term infant population, a level that the comment characterized as the limit of detection.

(Response) FDA notes that the limit of detection of the analytical method the Agency uses to detect the presence of *Cronobacter* spp. is 1 CFU/100 g of powdered infant formula. The Agency will consider an infant formula to be adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the FD&C Act if the pathogen is detected at this level or higher using the analytical method required by this interim final rule for determining compliance with the M value in § 106.55(e).

For the following reasons, FDA declines to adopt the suggestion of this comment. First, this comment predates FDA's announcement of its tentative decision in the 2006 reopening to establish a microbiological standard for *Cronobacter* spp. of negative (i.e., no organisms) in 30 X 10 g. As discussed previously in this document, this standard should protect both premature and term infants. Although it proposes a slightly different standard, the comment does not directly challenge the interim final rule's standard of 30 X 10 g. Second, on a 100 g basis, FDA's final microbiological standard for *Cronobacter* spp. (negative in 30 X 10 g) is slightly higher than the standard suggested in this comment (0.36/100 g). FDA has determined that a standard of 30 X 10 g is adequate to protect all infants.

ii. *Other issues regarding the sampling plan.*

(Comment 139) Several comments asked for clarification about whether the "30 x 10 g" refers only to the sampling plan, and that the testing required would consist of one test of a composited sample.

(Response) FDA is clarifying that the 30 individual samples of 10 g each are to be combined, for purposes of testing, into one 300 g sample composite. FDA emphasizes that that when sampling, a

manufacturers must collect 30 individual samples of 10 g each randomly from each production aggregate of finished product and may not take a single sample of 300 g because a single sample consisting of 300 g would not be considered representative of the production aggregate.

(Comment 140) One comment stated that while sampling large batches of product can be problematic, and product sterility cannot be absolutely assured, all powdered formula should be *E. sakazakii* (*Cronobacter* spp.) free.

(Response) FDA believes that this comment does not fully understand the standard proposed for *Cronobacter* spp. The standard that FDA proposed in the 2006 reopening is negative for *Cronobacter* in 300 g (30 x 10 g samples) of composited formula. This means that there must be less than one CFU in the 300 g sample. Said differently, a sample will be considered positive (and the production aggregate of infant formula will be considered adulterated) if one or more CFUs of *Cronobacter* are found in the 300 g sample.

The Agency agrees that, based on current technologies, it is not possible to produce a sterile powdered infant formula. For this reason, the interim final rule does not establish a zero tolerance for *Cronobacter* spp. However, by sampling and testing final production aggregates, as required in this interim final rule, product contamination with this pathogen will be minimized and public health protection maximized.

(Comment 141) One comment stated that the sampling plan proposed in the 2006 reopening is designed for use on large batches in continuous process manufacturing, that, in contrast, exempt infant formulas are often produced in small distinct batches, and that select sampling and testing programs that are relevant to exempt infant formulas to ensure the safety of the finished exempt formulas are preferable.

(Response) FDA notes that the requirements in this interim final rule, including the microbiological testing and sampling requirements, do not govern the manufacturing of exempt infant formulas. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance that addresses recommendations concerning how these CGMP should be applied to the exempt infant formulas.

d. *A microbiological standard for Cronobacter spp. for powdered infant formula consumed by premature and newborn infants.*

Some of the following comments were addressed in the 2006 reopening (71 FR 43392 at 43394).

(Comment 142) Some comments urged FDA to adopt the same standard for formulas intended for term infants and formulas intended for premature infants because a risk of *E. sakazakii* (*Cronobacter* spp.) infection exists in both populations.

(Response) FDA agrees with the comments that, with respect to non-exempt infant formula, consumption of powdered infant formula by infants of any age poses a risk of illness from *Cronobacter* spp. and therefore, all such formula should be subject to the same microbiological standards.

(Comment 143) Some comments addressed the need for a microbiological standard for exempt infant formulas, as defined in § 107.3, and asserted that, due to FDA's statutory authority under section 412(h)(2) of the FD&C Act to establish terms and conditions for the exemption of formulas intended for infants who are low birth weight or who have unusual medical problems, any effort to establish stricter microbiological requirements for these formulas should be done with a separate notice and comment rulemaking.

(Response) FDA notes that exempt infant formulas are not required to comply with this interim final rule. The Agency further notes that many exempt formulas are liquids and are already required to comply with part 113 because they are thermally processed low-acid foods packaged in hermetically sealed containers or part 114 because they are acidified foods. As such, these liquid formulas are commercially sterile products. However, there are a few exempt infant formulas that are powdered products, such as those for inborn errors of metabolism, which are not sterile. Because the risk of contaminated powder exists with these products, elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance that addresses recommendations concerning how these CGMP should be applied to the exempt infant formulas.

(Comment 144) One comment stated that there is no need to establish a more stringent standard for formula intended for premature or newborn infants as it would be impractical to differentiate between formulas as many of them are consumed by both full term and premature infants. Another comment recommended that the standards regarding powdered formula be the same for premature and term infants. The comment contended that the absolute risk of serious illness, even to term infants, is not zero. The comment also asserted that powdered formula products should not be consumed by premature infants before 44 weeks gestational age, or by any immunocompromised child, and that, with few exceptions (amino acid and metabolic formulas), "commercially" sterile liquid products are available for these populations. The comment noted, however, that it is not possible to eliminate completely powdered human milk fortifiers fed to premature infants, because many premature infants are unable to tolerate the added volume of liquid fortifier.

(Response) To the extent that the comment is referring to non-exempt infant formulas, FDA agrees that, as a practical matter, it would be difficult to limit formula consumption by certain infant subgroups to a specific type of formula unless the infants are directly under medical supervision because powdered infant formula intended for newborns and term infants may also be fed to premature infants. Thus, it is essential that non-exempt powdered formulas, whether fed to newborns, term infants, or premature infants, meet the same microbiological standards. As noted, the data clearly implicate powdered infant formula, a potential source of contamination from *Cronobacter* spp. and *Salmonella* spp. for all infant groups (see discussions in section V.J.2.b). The standard established by this interim final rule will be protective of infants consuming non-exempt infant formulas, regardless of gestational age.

The Agency notes, however, that infant formulas, including human milk fortifiers, that are represented and labeled as being for infants with inborn errors of metabolism, low birth weight, or infants with other unusual medical or dietary problems are exempt infant formulas and, as such, are not subject to the CGMP in this interim final rule. Although many of the exempt infant formulas are commercially sterile liquids, some are, as noted in the comment, powdered formulas and are not commercially sterile. As noted, elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance that addresses how these CGMP should be applied to exempt infant formulas.

(Comment 145) Some comments contended there should be a heightened standard for formulas intended for certain sub-populations of infants, including infants who are premature, of low birth weight, ill, or among a group described as vulnerable hospitalized infants. Several of these comments argued that there should either be no

standard or a lower standard for formulas intended for other infants.

(Response) To the extent that this comment is referring to standards for exempt infant formulas (i.e., formulas represented and labeled for use by infants who have an inborn error of metabolism, low birth weight, or unusual medical or dietary problems), such products are not, as noted previously in this document, subject to the requirements of these CGMP FDA is publishing a notice of availability of a draft guidance that addresses how to apply these CGMP, including microbial testing standards, to such formulas. FDA notes that it is possible that a number of subgroups of infants, including those term infants who are ill or hospitalized, may be fed a non-exempt infant formula, and that the microbiological standards in this interim final rule are sufficiently protective of such subgroups of infants.

FDA disagrees with the comment that suggested no standard or a lower standard for formulas intended for "other infants," to the extent that "other infants" refers to "term infants," for the reasons discussed in section V.J.2.b.i.

(Comment 146) One comment asserted that formulas for premature infants or infants with gastrointestinal medical conditions should receive specific and elevated testing. The comment argued that although microbiological testing by formula manufacturers has generally been sufficient for such infant populations in the past, there have been changes in the infant population consuming powdered formula. In particular, the comment claimed that premature infants are now viable at "micro weights" and extreme prematurity of less than 23 weeks gestation; these infants are more susceptible to microbial infection. The comment asserted that a more rigorous standard may be needed for powdered products designed for feeding low birth weight infants or some vulnerable hospitalized infants, although even in these cases, mishandling of formula during reconstitution, feeding, and storage may increase the risk of disease.

(Response) FDA notes that this comment preceded the 2006 reopening and the Agency's tentative determination to establish a standard for *Cronobacter* spp. in powdered infant formula. Thus, the comment was not directly challenging the adequacy of the microbiological standards proposed at that time.

The Agency acknowledges the comment's concerns about the safety of formula fed to very low weight premature infants but, as explained in Comment 143, the formulas that are subject to this rulemaking are the non-exempt infant formulas (i.e., formulas that are not represented and labeled for infants that have an inborn error of metabolism, low birth weight, or other unusual medical or dietary problem.) FDA is aware that some premature infants may be fed the same powdered infant formulas that are consumed by term infants and thus, are vulnerable to infection from *Cronobacter* spp. and *Salmonella* spp., if these organisms are present in the formula. The microbiological standards established in § 106.55(e) of the interim final rule for non-exempt infant formulas are designed to provide and will provide adequate protection for both premature and term infants who consume them. To the extent that this comment concerns exempt infant formulas, FDA notes that such powdered exempt formulas are not subject to the standards of this interim final rule. While it may be appropriate at some future date to propose a separate standard for some or all exempt infant formulas, the Agency declines to do so at this time. As noted, the agency is concurrently issuing draft guidance on how the CGMPs should apply to exempt infant formulas.

FDA has carefully considered all of the comments that support two standards for non-exempt infant formulas—one standard for formula intended for premature and newborn infants and one for formula intended for infants beyond the newborn period and finds that it is neither necessary nor feasible to establish a more stringent *Cronobacter* spp. standard or a more stringent *Salmonella* spp. standard for non-exempt powdered infant formula consumed by premature and newborn infants. For the reasons cited previously in this document, FDA concludes that the standards established in § 106.55(e) of the interim final rule for *Cronobacter* spp. and for *Salmonella* spp. apply to all non-exempt powdered formulas intended for infants from birth to 12 months of age and that both such standards are sufficiently protective of such infants.

(Comment 147) A few comments asserted that formulas for premature infants or infants with gastrointestinal medical conditions should be labeled to inform families and practitioners that the product is not sterile. One comment added that the label should state that the product should not be given to immunocompromised babies.

(Response) Comments regarding the labeling of formula for premature or immunocompromised infants are beyond the scope of this interim final rule. Importantly, however, FDA notes that a variety of educational and other outreach programs have been established to communicate the proper use, preparation, and handling of powdered infant formula, including outreach by the AAP and ADA to their members.

e. *Elimination of microbiological standards for Aerobic Plate Count, Coliforms, Fecal Coliforms, Listeria monocytogenes, Staphylococcus aureus, and Bacillus cereus.*

In the original 1996 proposal, FDA proposed to establish seven microbiological quality standards for powdered infant formula: APC, coliforms, fecal coliforms, *Listeria monocytogenes, Staphylococcus aureus, Bacillus cereus,* and *Salmonella* spp. At the time of the proposal, the microorganisms for which FDA proposed standards were those of known public health significance or were viewed as indicators that a formula was prepared, packed, or held under insanitary conditions (62 FR 36154 at 36170).

Subsequently, in the 2003 reopening, the Agency requested comment on the need for a standard for *Cronobacter* spp., an emerging pathogen associated with severe illness in certain formula-fed infants. Thereafter, in the 2006 reopening, FDA announced the Agency's tentative conclusion not to finalize the microbiological testing regime proposed in 1996 and to limit required final product testing of powdered infant formula to only two microorganisms, *Cronobacter* spp. and *Salmonella* spp. Based on the available evidence, including the 2004 and 2006 FAO/WHO expert consultations, the Agency tentatively concluded that only *Cronobacter* spp. and *Salmonella* spp. had been associated with infant illness related to microbiological contamination of powdered infant formula (Ref. 2). In the 2006 reopening, FDA also explained that testing for an indicator organism, such as *Enterobacteriaceae*, can be beneficial to manufacturers in monitoring their overall process and production sanitation (71 FR 43392 at 43396) but the Agency's tentative decision was not to require such testing.

Several comments supported the Agency's tentative determination to establish microbiological standards only for *Cronobacter* spp. and *Salmonella* spp. in finished powdered infant formula product. One comment noted that *Listeria monocytogenes* and *Staphylococcus aureus* have not been problems for the U.S. formula industry. In addition, several comments made in response to the 1996 proposal challenged the proposed requirement to test each batch (production aggregate) of

powdered infant formula at the final product stage for the microorganisms listed in proposed § 106.55(c) and thus, indirectly supported FDA's tentative determination not to finalize certain of the proposed standards. Other comments objected to FDA's tentative plans to revise proposed § 106.55.

(Comment 148) One comment questioned FDA's tentative conclusion in the 2006 reopening that only *E. sakazakii* (*Cronobacter* spp.) and *Salmonella* spp. are of concern in infant formula.

(Response) FDA is confirming its tentative decision announced in the September 2006 reopening not to finalize the proposed microbiological standards for APC, coliforms, fecal coliforms, *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus.* FDA notes that this comment provided no data or other information to contradict the Agency's tentative conclusion that protection of the public health does not require establishing microbiological standards and testing for organisms other than *Cronobacter* spp. and *Salmonella* spp. The basis for the decision not to finalize all of the proposed requirements is discussed in detail in this document.

Aerobic Plate Count, Coliforms, and Fecal Coliforms: The 1996 proposed rule would have required infant formula manufacturers to conduct tests for APC, coliforms, and fecal coliforms. In the proposal, FDA noted that these three microbiological standards had a specific purpose: an M value exceeding the proposed standard would imply that the formula was produced under insanitary conditions whereby the formula may have been rendered injurious to health and thus, the formula could be adulterated under section 402(a)(4) of the FD&C Act. (Such use of microbiological testing is often referred to as "indicator organism" testing.) The Agency acknowledged that all three tests were capable of identifying both pathogenic and non-pathogenic microorganisms, and the proposal did not specifically identify any evidence that pathogenic organisms that would be identified by these three tests had previously been linked to formula-borne illness in infants.

FDA has concluded that, on balance, it is not necessary or appropriate to finalize standards for APC, coliforms, and fecal coliforms because in the context of the complete interim final rule, including the required microbiological testing scheme, these tests are not essential and the proper interpretation of the results of such testing is not at all clear.

As discussed in section V.C. 2, § 106.6 of the interim final rule requires a manufacturer to implement a system of production and in-process controls designed to prevent adulteration, including adulteration due to insanitary conditions. The decision to conduct "indicator organism" testing (such as APC and testing for coliforms and fecal coliforms) is best made on a facility-by-facility basis and in the context of a manufacturer's entire production and in-process control system. Thus, to the extent that a particular manufacturing process requires or would otherwise benefit from the application of indicator organism testing, such as APC or testing for coliforms or fecal coliforms, as a means to control adulteration from insanitary conditions, the manufacturer's plan may, and should, include such testing. Accordingly, FDA declines to finalize standards for APC, coliforms, and fecal coliforms that would apply to all manufacturers regardless of the process control systems. Not finalizing the requirements for APC and coliforms and fecal coliforms testing will not increase the risk of illness to infants. As noted, the three tests do not distinguish between pathogenic and non-pathogenic microorganisms so they cannot be used to identify organisms that theoretically could contaminate powdered infant formula with pathogens.

Moreover, as discussed in detail previously in this document, the interim final rule mandates that each production aggregate of finished infant formula be analyzed for the two pathogenic organisms that have a documented association with powdered infant formula, *Cronobacter* spp. and *Salmonella* spp. Thus, the interim final rule requires specific controls to prevent the direct microbiological contamination of formula with these pathogens. Although a variety of *Enterobacteriaceae* have been isolated from powdered infant formula, including *Citrobacter koseri, Klebsiella pneumoniae, Klebsiella oxytoca, Pantoea agglomerans,* and *Enterobacter cloacae,* and are capable of causing illness, none have been demonstrated to have done so (Ref. 2). In contrast, *Salmonella enterica* (Ref. 57), *Salmonella virchow* (Ref. 58), and *Cronobacter* spp. are associated with illness in infants (Refs. 24, 34, 59). Also, to the extent that testing for *Cronobacter* spp. or *Salmonella* spp. documents contamination of a production aggregate of finished formula, as discussed in this document, other provisions of the interim final rule require controls to prevent microbial contamination that would adulterate the infant formula.

Section 106.6(c) of the interim final rule requires that a manufacturer establish specifications at any point, step, or stage in the production process where control is necessary to prevent adulteration. Therefore, a manufacturer that determines that a specification for indicator organism testing results is a necessary as part of its system of production and in-process controls in order to prevent adulteration is required to establish such a specification. If a manufacturer's testing of its facility documents levels of APC, coliforms, or fecal coliforms under circumstances that establish the presence of insanitary conditions in the facility that would adulterate the infant formula, and the manufacturer has either not included indicator organism testing in its plan under § 106.6(a) of the interim final rule or has not established specifications for such indicator organisms, the presence of such organisms at such levels and the absence of established specifications for such organisms would be a violation of § 106.55(a) of the interim final rule.

Moreover, the interim final rule requires investigation and evaluation of the circumstances that result in a failure to meet specifications, including the microbiological standards of the interim final rule. Specifically, § 106.70(b) of the interim final rule requires quarantine of the contaminated formula and a documented review and a material disposition decision for the formula. Similarly, § 106.100(e)(4)(iii) of the interim final rule requires a manufacturer to maintain a record of the investigation and follow-up of such failure. FDA expects that part of a manufacturer's investigation and follow-up to a finding of actual contamination of formula will be the evaluation of the manufacturing environment to determine whether insanitary conditions may have contributed to the microbiological contamination of the production aggregate and the identification and implementation of appropriate corrective actions.

For these reasons, FDA declines to finalize the proposed requirements for APC and for coliforms and fecal coliforms testing in proposed § 106.55(c).

Listeria monocytogenes, Staphylococcus aureus, and Bacillus cereus: Proposed § 106.55(c) would have required infant formula manufacturers to conduct tests of finished powdered infant formula for *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus.* In the proposal, FDA noted that "health concerns may arise due to the presence of any

detectable . . . *Listeria* or *S. aureus* bacteria in infant formula or due to levels of *B. cereus* that exceed 1,000 'colony-forming units' (CFU's) per gram (g) of a powdered formula." (61 FR at 36170). In making this statement, the Agency did not cite specific data or other information documenting the contamination of powdered infant formula with any of these microorganisms.

More recently, in the 2006 reopening, FDA tentatively concluded, based on the data developed during the FAO/WHO expert consultations, that testing for these three organisms was not warranted to ensure microbiological safety of powdered infant formula (Ref. 3). The report of the 2004 FAO/WHO expert consultation sorted the microorganisms of possible concern in infant formula into three categories; *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus* were placed in the category "causality less plausible or not yet demonstrated" because the organisms had not been identified in powdered formula (*Listeria monocytogenes, Staphylococcus aureus*) or because no causal association between the organism and illness from powdered formula had been demonstrated (*Bacillus cereus*) (Ref. 2). The report of the 2006 expert consultation affirmed this categorization (Ref. 3). Moreover, FDA is not aware of any data or other information showing that these organisms are present in powdered infant formula or, if present, have been associated with infant illness.

Several comments supported FDA's tentative determination to not finalize the microbiological standards for *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus,* with one comment noting that *Listeria monocytogenes* and *Staphylococcus aureus,* have not been problems for the U.S. formula industry. However, as noted, one comment objected to FDA's proposal to delete microbiological standards for *Listeria monocytogenes, Staphylococcus aureus,* and *Bacillus cereus* although no data were submitted to support this objection.

(Comment 149) Several 1996 comments argued that testing for *Listeria monocytogenes* was unnecessary because this organism does not pose a significant health concern in infant formula.

(Response) FDA agrees with this comment and, as noted, is not finalizing the proposed *Listeria monocytogenes* microbiological standard for powdered infant formula. The Agency's decision on this point is supported by the conclusions of the recent FAO/WHO expert consultation.

(Comment 150) One 1996 comment requested that FDA change the M value for *Bacillus cereus* to 1,000 most probable number/g (MPN/g) because there is no health concern associated with the proposed level of 100 MPN/g.

(Response) FDA is not finalizing the proposed microbiological standard for *Bacillus cereus* in powdered infant formula. As noted, the recent FAO/WHO expert consultation concluded that there is no documented association between *Bacillus cereus* and illness from consumption of powdered infant formula, a conclusion with which the Agency agrees. Thus, the suggestion that the M value for *Bacillus cereus* be revised is moot.

(Comment 151) One comment requested that FDA replace the standards for coliforms and fecal coliforms with one for *E. coli* due to the possibility of improper interpretation of coliform and fecal coliform tests.

(Response) As noted, FDA is not finalizing the proposed microbiological standard for coliforms and fecal coliforms in powdered infant formula because the Agency has determined that the decision to use certain organisms as indicators of insanitary conditions, including coliforms and fecal coliforms, should be made on a case-by-case basis by each manufacturer in the context of the manufacturer's overall plan to control adulteration and baseline data developed for the facility. Thus, the suggestion that a test for *E. coli* be substituted for the coliforms and fecal coliforms testing is moot.

(Comment 152) One comment recommended an *Enterobacteriaceae* standard of 3.0 MPN/g as a substitute for coliforms.

(Response) FDA notes that the comment did not provide the reasoning to support the use of this standard. The Agency is not finalizing the proposed microbiological standard for coliforms in powdered infant formula. Thus, the suggestion that a standard for *Enterobacteriaceae* of 3.0 MPN be substituted for the coliforms standard is moot.

(Comment 153) Several comments expressed concern about the Agency's interpretation of "unhygienic conditions" and adulteration with respect to a positive finding for a microorganism other than *Cronobacter* spp. and *Salmonella* spp. The comments asserted that language in the 2006 reopening (71 FR 43392 at 43397) advised that the presence of any level of the identified organism would be sufficient to conclude that a formula is adulterated. Thus, one comment suggested that "unhygienic conditions" be defined through guidance criteria. Another comment asserted that, in the absence of any standard for these other microorganisms, FDA was establishing a zero tolerance for these microorganisms and that elimination of all organisms is not be feasible at this time.

(Response) FDA is restating its views on microbiological test results and conclusions about insanitary conditions that lead to adulteration of food.

As noted in the comment, in the 2006 reopening, FDA stated that "the presence of these microorganisms in an infant formula reflects that the formula was prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health and therefore is adulterated under section 402(a)(4) of the FD&C Act." This statement appears to suggest that the violation of one of the proposed microbiological standards (*i.e.,* APC, coliform, fecal coliform test, *Listeria monocytogenes, Staphylococcus aureus, Bacillus cereus,* or *Enterobacteriaceae*) would categorically establish adulteration under section 402(a)(4) of the FD&C Act.

In fact, FDA generally considers any microbiological test results as well as any other CGMP observations when considering whether a food has been processed under insanitary conditions. Moreover, as noted in the 2006 reopening, the tests for several of these organisms (APC, coliforms, fecal coliforms, and *Enterobacteriaceae*) do not distinguish between pathogenic and non-pathogenic organisms (71 FR 43392 at 43396) so it is difficult to interpret the meaning of any positive results in the absence of baseline data, either for the infant formula industry generally or specific to individual infant formula production facilities. Accordingly, FDA has no current plans to define "unhygienic conditions" in an Agency guidance document.

Finally, for reasons comparable to those stated in the response to Comment 121, FDA does not agree that the Agency is setting a zero tolerance for any microorganism either in infant formula or in the formula processing environment. Accordingly, FDA has no current plans to define "unhygienic conditions" in an Agency guidance document.

(Comment 154) One comment suggested that FDA not repeat the statement regarding adulteration as written in the 2006 reopening (71 FR 43392 at 43397), which referred to adulteration in the context of finding any of the other pathogens present, and suggested the following statement "the presence of certain food borne pathogens in an infant formula at levels (concentrations) known to be of public

health significance establishes that the formula may have been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health and therefore is adulterated."

(Response) In responding to Comment 148, FDA has clarified its views on the significance of the presence of microorganisms other than *Cronobacter* spp. and *Salmonella* spp. in powdered infant formula and the infant formula processing environment and adulteration under section 402(a)(4) of the FD&C Act. Accordingly, it is unnecessary to adopt the statement suggested in the comment and FDA declines to do so.

f. *Comments on testing methodology.*

(Comment 155) One comment expressed concern with the provision in proposed § 106.55(c) that states that the Agency will determine compliance based on the methods cited in the Bacteriological Analytical Manual. The comment stated that a comparison of the BAM and a method used by the USDA for the determination of *Listeria monocytogenes* concluded that neither method provided a greater detection of efficiency for isolating *Listeria monocytogenes* from all types of foods. However, the comment recommended that FDA consider the use of other official, recognized methods, such as the USDA method, to reduce the testing time and consequent costs without detriment to compliance.

(Response) As discussed previously in this document, FDA has determined that the interim final rule need not contain a microbiological standard for *Listeria monocytogenes* in final product powdered infant formula. Thus, this comment no longer requires a response.

(Comment 156) One comment pointed out that AOAC International Association of Official Analytical Chemists should be changed to AOAC International, in proposed § 106.55(c).

(Response) Section 106.55 of the interim final rule does not refer to the AOAC and thus, there is no need to update the organization's name as requested.

g. *Microbiological standard to ensure the safety of powdered infant formula if microorganisms are intentionally added to the formula.*

(Comment 157) Several comments discussed the effect of intentionally added microorganisms ("probiotics") on the testing for compliance with microbiological standards. One comment asserted that it is not clear that the addition of beneficial organisms would have any negative impact on the proposed microbiological requirements and that while it is possible that some infant formulas supplemented with probiotics might exceed the APC, others, such as those containing anaerobic bacteria, would not. Thus, the comment suggested that FDA exempt formulas containing these organisms from the APC limit as long as the manufacturer employed sanitation indicative testing, such as testing for *Enterobacteriaceae*. Other comments suggested that for these probiotic-containing formulas, FDA require automatic testing for organisms such as *B. cereus* that is usually only required when the formula exceeds the APC. One comment claimed that this additional testing would be similar to the currently recommended evaluation of cultured dairy products. Another comment requested that any final regulation acknowledge that probiotic formulas would require exemption for APC limits or any other proposed criteria for assessing insanitary conditions. One comment suggested that, to ensure that a high APC is caused by the added probiotic organism and not by contamination of the formula, there would need to be a two-stage testing procedure: Prior to addition of the probiotic organism, the bulk product would have to be sampled and the APC measured, and then selective microbiological test regimes would have to be carried out on final packaged product.

(Response) In the 2006 reopening, FDA stated it was not aware of any marketed infant formula in the United States that contained intentionally added microorganisms and tentatively decided not to consider requirements related to such formula (71 FR 43392 at 43396). Since that time, powdered infant formulas containing intentionally added microorganisms have entered the U.S. market.

As discussed earlier in this section, FDA has decided not to finalize the requirement for an APC count in proposed § 106.55(c). Under § 106.55(a) of the interim final rule, a manufacturer of a formula to which microorganisms have been intentionally added must ensure that the formula does not become adulterated due to the presence of microorganisms or in the processing environment. In addition, as discussed previously in this document, under § 106.6(c) of the interim final rule, a manufacturer must establish specifications where control is necessary to prevent adulteration, including a specification for intentionally added microorganisms. Thus, a manufacturer would need to evaluate the potential for any intentionally added organisms to interfere with the ability to detect *Cronobacter* spp. *and Salmonella* spp., and should have data to demonstrate the absence of such interference in order to establish that the formula meets the microbiological standards in § 106.55 of the interim final rule. Moreover, manufacturers would have to ensure that the presence of microorganisms is due to the intentional addition of such microorganisms, based on the master manufacturing order, and not to contamination.

(Comment 158) One comment stated that manufacturers should do specific culturing and identification of the intentionally added bacteria, not just plate counts.

(Response) Although FDA is not finalizing the requirements for APC testing, FDA emphasizes that a manufacturer needs to know the identity and quantity of any microorganism that it is adding to a formula. FDA agrees that any microorganism intentionally added to an infant formula should be identified by genus, species, and strain through testing of the final production aggregate to confirm that the organism present is the organism added and is present in the intended amounts. For example, if *Bifidobacterium lactis* strain Bb12 is added during production, testing must demonstrate that the final production aggregate contains the microorganism in the intended amount.

(Comment 159) One comment stated that testing would need to be specific for the type of organism added and requested that "any final regulation acknowledge that validated methods for testing probiotic formulas will need to be decided between the manufacturer and FDA as part of the pre-market review process."

(Response) As stated in the response to Comment 158, FDA agrees that testing needs to be specific to the type of microorganism intentionally added to a formula. In subpart C (see section VI.A.1 of this preamble), FDA addresses the use of "validated" test methods for nutrient testing. It is appropriate to apply a similar construct to the use of microbiological test methods used to confirm the identity and amount of intentionally added microorganisms. A manufacturer may use any method that is accurate, precise, and specific for its intended purpose, and thus, methods for intentionally added microorganisms should not be restricted to FDA official BAM methods or other methods formally validated in a multi-laboratory collaborative study.

(Comment 160) One comment suggested that because sampling and testing for microbiological endpoints continue to lead to variability, and thus

uncertainty of results, FDA should define sampling and testing methods in association with establishing microbiological specifications as proposed by International Commission on Microbiological Specifications for Foods (ICMFS), and recognized by Codex, as an option.

(Response) FDA disagrees with this comment. First, the comment did not explain how testing for microbiological endpoints would continue to lead to variability and uncertainty of results. Second, the Agency does expect that a manufacturer's sampling plan for an intentionally added microorganism will have an appropriate statistical basis and will take into account any variability in distribution of the microorganism in the production aggregate. FDA has no objection to the use by a manufacturer of a testing method proposed by ICMFS for intentionally added microorganisms as long as the method is valid, that is, the methods are scientifically sound, accurate, precise, and specific for its intended use. Accordingly, FDA is not defining in this interim final rule the specific sampling and analytical method(s) that should be used for intentionally added microorganisms. Intentionally added microorganisms have to meet the specifications set by manufacturers for such ingredients, as would any ingredient added to an infant formula. As discussed earlier in this preamble, manufacturers must characterize the formula that they intend to produce, institute adequate controls to produce that formula, and ensure that the controls work so that the desired formula is consistently produced and is not adulterated.

(Comment 161) Several comments questioned the safety of intentionally added microorganisms. One comment expressed concern particularly with the use of these substances in formula intended for preterm infants with underdeveloped gastrointestinal barriers. Another comment suggested the need for a large clinical trial on both term and preterm infants to uncover unwanted side effects. One comment expressed opposition to the addition of *Bifidobacterium* and *Streptococcus* intended for use in infant formulas for infants over the age of four months because of concern about the GRAS status of these microorganisms, the risk-benefits, and the unknown biological effects of these organisms on the microflora in the infants' intestines. This comment also expressed concern regarding the unknown effects of manipulation of the infants' intestines and how these organisms might affect the infants' developmental processes. The comment further stated that although there have been reported beneficial effects of these microorganisms, the mechanisms of these effects are not known nor have long-term adverse effects been entirely excluded. The comment also stated that there is a risk that infants not in the intended use group would receive this formula as there is presently no formula on the market that is only intended for infants over four months of age.

(Response) Comments relating to the safety of microorganisms added to infant formula are beyond the scope of this rule. As discussed previously in this document, the safety of ingredients of all substances added to food, including microorganisms intentionally added to infant formula, is governed by sections 409 and 201(s) of the FD&C Act, and FDA expects that a formula manufacturer will ensure that the safety of any formula ingredient is appropriately established prior to using the ingredient in a formula product. FDA emphasizes that it is the manufacturer's responsibility to ensure the safety of the all food ingredients, including microorganisms added to infant formula.

K. Controls To Prevent Adulteration During Packaging and Labeling (Proposed § 106.60)

In 1996, FDA proposed in § 106.60 to require that an infant formula manufacturer implement specific controls designed to prevent adulteration during the packaging and labeling of infant formula. The proposed provisions included requirements for the examination of packaged and labeled formula, label design and application, and packaging of multiple container units of formula.

The Agency received comments on several aspects of proposed § 106.60, which are addressed in this document. Section 106.60 of the interim final rule includes minor editorial revisions as well as the changes discussed in this document that are made in response to comments.

1. Labels Designed To Remain Legible and Attached During Use (Proposed § 106.60(b))

(Comment 162) Several comments requested that the phrase "and use" be deleted from proposed § 106.60(b), which would require that labels be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use. These comments noted that some infant formula product labels are designed to be removed by the end user because the backs of the labels are printed with use information (such as use instructions in a foreign language) or coupons. One comment contended that this proposed requirement would prohibit providing useful information to the consumer.

(Response) The purpose of proposed § 106.60(b) is to ensure that a formula label is designed and applied so that the label cannot easily become detached during processing, storage, handling, distribution, and use. Importantly, however, FDA would not object to a label that is designed and applied to a formula product so that a consumer could purposefully remove the label, so long as the label is otherwise designed and applied to remain attached to the infant formula container under reasonably expected conditions of use. FDA is concerned that removing the phrase "and use" from proposed § 106.60(b) would permit a manufacturer to design and apply a label that would not remain attached or legible under reasonably expected conditions of use. For example, with the suggested revision, a manufacturer could use a label adhesive that dissolves when dampened. For this reason and in light of the foregoing clarification, FDA declines to modify § 106.60(b) in the interim final rule in response to these comments.

2. Multiple Container Packages (Proposed § 106.60(c))

Several comments objected to proposed § 106.60(c), which would require that all infant formula held in a single package be the same product bearing the same code. In the preamble to the proposal, FDA explained how these proposed packaging requirements would make it more difficult for counterfeit formulas, or formula with counterfeit labels, to be shipped in interstate commerce (61 FR 36154 at 36173).

(Comment 163) One comment requested that FDA make a distinction in the preamble to the final rule between counterfeiters and diverters. The comment explained that diverters are part of the normal distribution channel for infant formula and are not counterfeiters. The comment stated that diverters generally purchase formula products in a geographic area where a special allowance or deal is being offered and then resell the products in an area where the deal is not offered. In such circumstances, the comment explained, the immediate formula containers retain the original manufacturer labels but several lots of the same product may be consolidated to fill a single shipping container. The comment requested that FDA remove all references to diverters in the proposal.

(Response) FDA did not intend to stymie distribution of formula or prohibit wholesaling or other legitimate marketing practices, including those of legitimate diverters as described in the comment. However, to ensure that, in the event of a product recall, all affected formula can be readily identified, it is imperative that all infant formula packaged in a single shipping container be completely and accurately identified. Only with such identification will recalled formula be traceable. As discussed in response to Comment 164, FDA is revising proposed § 106.60(c) to permit, in certain limited circumstances, mixed lot packages of infant formula.

(Comment 164) Several comments asserted that proposed § 106.60(c) would prohibit manufacturers from making discharge packages or "kits" that contain samples of different products with different codes. One comment explained that these packages, which are commonly used by the infant formula industry to familiarize new parents with infant formula prior to an infant's discharge from the hospital, are designed to hold samples of different products and thus, necessarily contain products with different manufacturing codes. According to this comment, individual discharge packages are assigned a unique lot number for traceability purposes. The comment concluded by asserting that FDA's intention is not to eliminate discharge kits, which would be a disservice to consumers and hospitals and would have a substantial impact on the marketing programs of formula manufacturers.

(Response) In proposing § 106.60(c), FDA did not intend to prohibit manufacturers from preparing and distributing hospital discharge packages of infant formula. The comments state that these discharge kits are labeled with a unique identification number. Under certain limited conditions, traceability can be assured even with a mixed-lot container of formula, such as a discharge kit. Therefore, FDA is revising proposed § 106.60(c) to allow infant formula to be packaged, in certain limited circumstances, in mixed-lot shipping packages and in hospital discharge packages. Importantly, however, these mixed-lot container packages will be required to bear complete and accurate identification about all infant formulas in the package or be labeled with a unique identification number that is linked to a record that identifies the product code required under § 106.80 for each container of infant formula product in the multiple container package.

L. Controls on the Release of Finished Infant Formula (Proposed § 106.70)

In 1996, FDA proposed to require in § 106.70 that infant formula manufacturers establish controls on the release of finished infant formula. In particular, the controls would require the manufacturer to hold or otherwise maintain control of finished formula until it was determined to conform to all specifications of the manufacturer. In addition, proposed § 106.70(b) would require any out-of-specification formula to be rejected, and any rejected formula that was reprocessed would be required to conform to all specifications before release. Finally, proposed § 106.70(c) would require an individual qualified by training or experience to investigate any out-of-specification finding.

FDA received comments on proposed § 106.70, specifically on § 106.70(b). The Agency has addressed these comments in section V.C.2, and proposed § 106.70 has been revised as described previously in this document.

M. Traceability (Proposed § 106.80)

In 1996, FDA proposed to require that infant formula manufacturers ensure traceability of their products by coding the finished products. Adequate coding will ensure product recovery in case of a formula recall. The Agency received no comments specifically on proposed § 106.80, and to the extent other comments (such as those on proposed § 106.60) indirectly raised concerns about proposed § 106.80, the Agency has addressed those comments earlier in this preamble.

Since publication of the proposed rule in 1996, FDA has acquired additional information about the production of infant formula. For example, the Agency has learned that liquid formula may be produced over more than a single day and that many formula manufacturers use a "continuous process" manufacturing approach for their formula products regardless of the final form of the product (e.g., liquid or powered). Thus, some parts of proposed § 106.80 are no longer appropriate. Accordingly, FDA has revised § 106.80 in the interim final rule to update this provision in light of current manufacturing methods in the formula industry. The provisions of § 106.80 of the interim final rule do not distinguish between infant formula that has been produced during a single day, and infant formula that has been produced over more than a single day. In addition to being more current, these changes will have the advantage of requiring the application of the same coding protocol to all forms of a manufacturer's products, resulting in more consistent coding for all products of the same brand or line.

N. Audits of Current Good Manufacturing Practice (Proposed § 106.90)

In 1996, FDA proposed to require that infant formula manufacturers conduct regularly scheduled audits of a firm's compliance with CGMP and stipulated that such audits be performed by a person with knowledge of all aspects of infant formula production and FDA's CGMP regulations but who has no direct responsibility for the matters being audited. The Agency received several comments on proposed § 106.90, which are addressed in this document.

(Comment 165) One comment stated that requiring that the auditor be knowledgeable in "all" aspects of infant formula production is a lofty expectation given the complexities of an infant formula production environment. The comment suggested that the auditor should possess a general knowledge of the areas being audited, but not the depth and extent implied by the word "all."

(Response) This comment does not fully understand the personnel qualification requirement of proposed § 106.90. The objective of an audit required under proposed § 106.90 would be to determine whether the manufacturer has complied with current good manufacturing practice. As with any audit, to be valid and effective, the auditor must have well-developed knowledge of the focus of his audit. In this case, this means that the individual conducting the audit must have in-depth knowledge of infant formula production as well as the regulations governing that process. FDA disagrees that this is a "lofty" expectation.

Importantly, however, the CGMP audit of a firm's infant formula production would not be required to be conducted by a single individual. Thus, a manufacturer may choose to utilize a team of auditors, each of whom has general knowledge of the formula production process as well as more detailed knowledge of a specific facet or facets of that process so that, collectively, the auditing team is knowledgeable in "all" aspects of infant formula production. Where a team of auditors is used to conduct a CGMP audit, the team member assigned to audit a specific facet or facets of the process must possess specialized, detailed knowledge of both that aspect of the process and the Agency regulations that apply to such facet or facets. Importantly, however, where one person conducts a manufacturer's

CGMP audits, that individual must possess comprehensive knowledge of all aspects of infant formula production and of the applicable CGMP regulations. The Agency is revising § 106.90 in the interim final rule to expressly allow a team of individuals to conduct an audit. In addition, the Agency is changing "education, training, and experience" to "education, training, or experience" because the Agency considers that each of these can independently provide an adequate basis for an auditor have the necessary knowledge and skills to perform an audit.

(Comment 166) Another comment agreed with the proposed requirement that an auditor must not have direct responsibility for the matters being audited, but took exception to the preamble statement that the auditor must have no "past involvement in the activities being audited." The comment contended that this requirement presents a dilemma if the auditor must have knowledge of infant formula production, but could have no past involvement where knowledge might have been gained. The comment recommended that a reasonable time (1 year) be established after which any concern about potential bias would dissipate and an auditor could evaluate an area of previous employment.

(Response) As explained in this document, FDA agrees in part with this comment. In order to be meaningful and function as an appropriate oversight tool for CGMP compliance, any audit, including an audit conducted under proposed § 106.90, must be as objective as possible. Thus, FDA proposed to require in § 106.90 that the individual conducting an audit (including an auditor who is an employee of the company) have no direct responsibility for the matters being audited. As FDA noted in the preamble to the 1996 proposal, "The requirement that the audit be performed by an individual who has no direct responsibility for the matters being audited is one way to ensure the objectiveness of the audit process. The person should be free of any past involvement in the activities being audited because the audit is intended to uncover any problems or shortcomings in the manufacturer's procedures. A person who has been involved may feel that finding problems will reflect poorly on his or her work" (61 FR 36154 at 36175).

FDA is persuaded, however, that there may be certain circumstances in which an auditor with prior involvement in the activities being audited could still perform an unbiased audit. Each situation must be evaluated on a case-by-case basis by the formula manufacturer to ensure that that the audit will be objective and free from bias. A manufacturer should determine that a proposed auditor is able to be objective and to exercise independent judgment and thus, should consider such factors as the scope of the employee's previous responsibilities, the time elapsed between the reassignment of the former responsibilities and the audit, and whether the audit will be conducted by this single individual or a team. Evaluating these types of factors can provide a manufacturer with reasonable assurance that an audit conducted by this individual will be independent of bias.

(Comment 167) One comment contended that firms would have to hire auditors from outside their company to perform audits since an individual could not audit his or her own area and it would be unlikely that one person would be knowledgeable in all areas of plant operations. The comment points out that hiring an outside auditor would be an added expense and suggests that auditing could be conducted as effectively by in-house auditors trained in auditing practices.

(Response) FDA disagrees that a firm would have to hire auditors from outside its company to perform audits. First, section 412(b)(2)(B)(iv) of the FD&C Act, which requires that audits "be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula," would not preclude an auditor being an employee of the manufacturer. Moreover, as noted in the responses to Comments 165 and 166, a manufacturer may employ a team approach to ensure that an audit is staffed by individuals with comprehensive knowledge of the infant formula production process and also, in certain circumstances, a manufacturer may utilize an individual to audit an area of his/her prior responsibility so long as the manufacturer determines that an audit by such individual would be objective and free of bias.

The Agency notes that proposed § 106.90 addressed both audit scheduling and audit personnel requirements. For clarity, FDA is dividing § 106.90 of the interim final rule into two sections. Section 106.90(a) of the interim final rule establishes the regularly scheduled audit requirement, and § 106.90(b) of the interim final rule establishes the requirements for auditing personnel. The Agency is also clarifying that audits must be performed frequently enough to ensure compliance with the regulations in subpart B.

VI. Subpart C—Quality Control Procedures

As noted in the introductory section of this preamble, in 1982, FDA established subpart B of part 106, Infant Formula Quality Control Procedures (47 FR 17016 April 20, 1982). These regulations were authorized by section 412 of the FD&C Act as it existed at that time. Section 412 of the FD&C Act was subsequently amended in 1986 (Pub. L. 99–570). Thereafter, in 1996, the Agency proposed to redesignate, revise, or remove parts of the current quality control procedures regulations. The proposed requirements related to nutrient testing, stability testing, quality control records, and quality control audits. In proposing these changes, the Agency sought to establish the minimum practices that infant formula manufacturers must implement to ensure that all batches (production aggregates) of infant formula that they produce contain the required nutrients at the required levels throughout the shelf life of the product.

FDA received several comments on proposed subpart C. These comments are summarized in this document along with the Agency's responses. In addition to the revisions to subpart C, FDA is making minor editorial revisions in this subpart. These editorial revisions include deleting the titles from the paragraphs in § 106.91, a change that will make § 106.91 of the interim final rule consistent with the rest of part 106.

A. General Quality Control (Proposed § 106.91)

1. Nutrient Testing on Each Production Aggregate of Infant Formula (Proposed § 106.91(a))[6]

In 1996, the Agency proposed to require nutrient testing at four separate stages during the production of formula. Specifically, FDA proposed to require the following testing: (1) Testing of any nutrient premix used by a manufacturer to ensure compliance with specifications; (2) testing of each production aggregate of the infant formula product for an indicator nutrient (as defined in proposed § 106.3) either during the manufacturing

[6] In the following discussion, FDA uses the term "nutrient" as defined in § 106.3(k) of the interim final rule (i.e., as "any vitamin, mineral, or other substance or ingredient that is required in accordance with the table set out in section 412(i)(1) of the FD&C Act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake (DRI), or that has been identified as essential for infants by FDA through a **Federal Register** publication.") This was also the proposed rule's definition of "nutrient" with a few minor editorial revisions.

process, after addition of the premix, or at the final product stage and before distribution; (3) testing of the final product stage and before distribution for vitamins A, E, C, and thiamin; and (4) testing during manufacturing or at the final product stage and before distribution for all required nutrients as well as for any added nutrient for which the manufacturer has not previously tested.

(Comment 168) One comment requested that FDA delete proposed § 106.91(a)(1), which would require the testing of any nutrient premix used by a manufacturer. The comment contended that FDA should eliminate the requirement for premix testing and require only end-product testing for infant formula.

(Response) FDA disagrees with the suggestion to eliminate premix testing because such revision would be inconsistent with section 412(b)(3)(B) of the FD&C Act. Section 412(b)(3)(B) of the FD&C Act requires that each nutrient premix used in the manufacture of an infant formula be tested for each nutrient required by section 412(i) of the FD&C Act that is contained in such premix and that the manufacturer relies on the premix to supply to ensure that such premix is in compliance with its specifications or any certification by a premix supplier. Moreover, "nutrient" is defined in § 106.3 as any vitamin, mineral, or other substance or ingredient that is set out in the table of required nutrients in section 412(i) of the FD&C Act, that is set out in such table as revised by FDA by regulation, or that is identified as "essential" for infants by FDA or the Food and Nutrition Board of the IOM. Thus, a manufacturer that adds a "nutrient" not otherwise required under section 412(i) of the FD&C Act would have been required to test for such nutrient under proposed § 106.91(a), if the nutrient is added as part of a nutrient premix and the manufacturer is relying on the premix to provide that nutrient. Accordingly, the Agency declines to revise proposed § 106.91(a)(1) in response to the comment. For increased clarity regarding the nutrients that must be tested, however, FDA is making a minor revision as reflected in § 106.91(a)(1) in the interim final rule by adding the parenthetical phrase "(required under § 107.100 or otherwise added by the manufacturer)" after the words "shall be tested" in § 106.91(a)(1). The Agency is also deleting the title in proposed § 106.91(a) to make this section consistent with the rest of part 106.

(Comment 169) One comment also objected to proposed § 106.91(a)(3), which would require that, because they are susceptible to degradation, vitamins A, C, E, and thiamin be tested at the final batch (production aggregate) stage. The comment asserted that these vitamins are not always susceptible to degradation because susceptibility of a particular vitamin to degradation is affected by formula pH and processing techniques and that when using an aseptic or dry mix process, vitamins A, E, and thiamin also degrade very slowly. The comment contended that use of a premix with appropriate levels of vitamins A, C, E, and thiamin, and analytical verification at final product stage by a premix tracer (i.e., an indicator nutrient) is sufficient to ensure compliance with required nutrient levels without analyzing for these vitamins at the final product stage. The comment further asserted that requiring 100 percent analytical testing at the batch (production aggregate) stage is burdensome because of the increased paperwork, the additional time required for analysis, and the need to hold the finished product pending the analytical results and that such testing will be extremely expensive, the cost of which will need to be passed on to the consumer.

(Response) FDA is not persuaded by this comment to revise proposed § 106.91(a)(3) because such revision would be inconsistent with section 412(b)(3)(A) of the FD&C Act. Section 412(b)(3)(A) of the FD&C Act requires that at the final product stage, each production aggregate (batch) of infant formula be tested for four specific vitamins (vitamins A, C, E, and B1 (thiamin)) to ensure that the formula is in compliance with section 412(b) and (i) of the FD&C Act. There are no exceptions for this testing requirement for formulas that arguably degrade more slowly due to product pH or the means by which the product is manufactured. Moreover, the comment did not assert that the testing required for vitamin C be stricken, apparently because the comment could not credibly argue that vitamin C degrades slowly. Accordingly, the Agency declines to revise proposed § 106.91(a)(3) in response to the comment, and proposed § 106.91(a)(3) is included in this interim final rule as proposed.

(Comment 170) One comment stated that the proposed regulation requires that all nutrients required to be in infant formula by § 107.100 must be tested at the final batch (production aggregate) stage, even though the nutrient premixes already would have been analyzed for all the nutrients that the manufacturer is relying on the premix to supply.

(Response) This comment appears to relate to proposed § 106.91(a)(4) and seems to suggest that this proposed provision should be modified. FDA is not persuaded by this comment to revise the proposed provision. Proposed § 106.91(a)(4) is directly authorized by section 412(b)(3)(C) of the FD&C Act (21 U.S.C. 350a(b)(3)(C)). Section 412(b)(3)(C) of the FD&C Act requires that during the manufacturing process or at the final product stage and before distribution, an infant formula be tested for all nutrients required by section 412(i) of the FD&C Act to be in the formula for which testing has not been done under section 412(b)(3)(A) or (b)(3)(B) of the FD&C Act. There are no exceptions from this testing requirement. A nutrient that is not otherwise tested as part of testing the premix or is required to be tested at the final product stage under § 106.91(a)(3) of the interim final rule is required to be assayed either during the manufacturing process or during the final product stage. Accordingly, the Agency declines to revise proposed § 106.91(a)(4) in response to this comment.

(Comment 171) One comment suggested that FDA modify proposed § 106.91(a)(4) to require that quality control testing be conducted using validated nutrient test methods to ensure the accuracy and precision of test results to determine compliance with the FD&C Act.

(Response) It is important to distinguish between "validated" test methods and "valid" test methods. The process of method validation is a formal process for demonstrating that an analytical procedure is suitable for its intended use. In contrast, a "valid" method is a method that is suitable for or capable of consistently achieving the intended results.

Typical validation characteristics include accuracy, precision, specificity, detection limit, quantitation limit, linearity, range, and robustness. Methods, such as AOAC International methods, are validated in collaborative studies using several laboratories under identical conditions; these methods are often described as "official [validated] methods." Method validation may also be conducted in a single laboratory by repeating the same test multiple times. Many analytical methods have been formally validated. However, other scientifically valid methods have not been subject to the formal validation process. For example, a test method not validated by a collaborative study using multiple laboratories may nonetheless be scientifically valid because it is, in fact, suitable for its intended purpose

and capable of consistently producing accurate results.

FDA disagrees with the comment's specific recommendation that proposed § 106.91(a)(4) be revised to require that quality control testing be conducted using validated nutrient test methods. It is scientifically sound to permit nutrient tests to use any method that is accurate, precise, and specific for its intended purpose and thus, permitted methods should not be restricted to official AOAC methods or other methods formally validated in a multi-laboratory, collaborative study.

Although FDA does not agree with the comment's specific recommendation, in light of the foregoing comment, it is appropriate to stipulate in the interim final rule a standard for nutrient testing methods. Accordingly, in this interim final rule, FDA is redesignating proposed § 106.91(c) "Quality control records" as § 106.91(d), and adding a new § 106.91(c) "Use of scientifically valid nutrient test methods." Section 106.91(c) of the interim final rule states that "All quality control testing shall be conducted using appropriate, scientifically valid test methods."

(Comment 172) One comment suggested revising proposed § 106.91(a)(4) to require that during the manufacturing process or at the final product stage, before distribution, each batch (production aggregate) be tested for "each nutrient" instead of for "all nutrients" required to be included in such formula under § 107.100.

(Response) FDA declines to make the revision proposed by this comment because the Agency is not persuaded that there is a sound reason to replace the reference to "all nutrients" by the phrase "each nutrient" in proposed § 106.91(a)(4). The comment provides no reason for this suggested change. The proposed requirement is consistent with the language in the statute in that section 412(b)(3)(C) of the FD&C Act requires testing for "all nutrients" required to be included in an infant formula for which testing had not been completed earlier in the manufacturing process. On this basis, FDA is not revising § 106.91(a)(4) in response to this comment.

(Comment 173) One comment requested that FDA delete the requirement in proposed § 106.91(a)(4) and (b) that the manufacturer test "for any nutrient added by the manufacturer" in addition to testing for the nutrients required by § 107.100. The comment contended that this testing requirement is without added benefit.

(Response) FDA disagrees. Nutrients are unique compounds and are needed at certain levels by the body for normal health. If an infant formula contains too little of a nutrient, a deficiency may occur in infants consuming the formula. Conversely, if an infant formula contains too much of a nutrient, toxic effects may occur.

Testing for nutrients not required under § 107.100 in each production aggregate of infant formula is consistent with CGMP and quality control procedures that are required to be established by section 412(b)(2)(A) of the FD&C Act. The preamble to the 1996 proposal explained why testing for these added nutrients is necessary for proper formulation of a formula as follows: "[I]t is important that the level of these added nutrients be controlled, and that the level of the added nutrient be consistent from batch to batch [production aggregate to production aggregate] and be uniform throughout the batch [production aggregate] of infant formula. The level of a nutrient needs to be controlled because some nutrients can be toxic to an infant if given at too high a level. Controlling the level of the added nutrient for consistency from batch to batch [production aggregate to production aggregate] and in a particular batch [production aggregate] of infant formula will ensure that the infant receives the essential nutrient on a consistent basis and will also ensure that the infant does not receive too high, or too low, a level of the nutrient because the nutrient was not uniform through the batch [production aggregate] of infant formula" (61 FR 36154 at 36176).

The comment does not dispute the reasoning of the 1996 preamble that supports the need to test formula at the final product stage to confirm the presence and level of a nutrient that is not legally required in but added to formula by the manufacturer. Furthermore, if health professionals or parents are selecting a particular infant formula because it contains a particular nutrient that is declared in the statement of nutrient amounts in the labeling and not currently required by § 107.100, it is important that the nutrient is present in the infant formula at the level stated in the product's labeling.

The concern about the testing for nutrients added but not required under § 107.100 is not simply theoretical. Infant formula manufacturers have voluntarily added the nutrient, selenium, to their infant formulas even though this nutrient is not currently required by § 107.100. Selenium has been identified by the IOM of the NAS as an essential nutrient for infants (61 FR 36154 at 36176) and, if added, may be declared in the statement of nutrient amounts in the formula labeling (§ 107.10(b)(5)). Selenium is necessary for health but is toxic at high doses (Ref. 60). Characteristics of morbidity resulting from both deficient and excess intakes were summarized in 2000 by the IOM (Ref. 60). Keshan disease, a cardiomyopathy that occurs almost exclusively in children, has been linked to selenium deficiency. Chronic selenium toxicity (selenosis) has also been observed in humans. Reported characteristics of such toxicity include gastrointestinal upsets, hair and nail brittleness and loss, skin rash, garlic breath odor, fatigue, irritability, and nervous system abnormalities. Although acute selenium toxicity is rare, the literature contains a few reports of acute fatal or near fatal selenium poisoning resulting from accidental or suicidal ingestion of selenium (Ref. 60). Given the adverse effects of too little or too much selenium, the IOM has established an adequate intake level and a tolerable upper intake level of selenium for infants.

As the sole source of nutrition for many infants, infant formula must provide appropriate amounts of all nutrients in the formula. Testing each production aggregate of infant formula for each nutrient at the final product stage will help to ensure that an infant formula consistently contains an appropriate amount of each nutrient.

For additional consideration of selenium in infant formula, see Comment 295 in section VIII.

For these reasons, FDA is not revising § 106.91(a)(4) in the interim final rule in response to this comment.

Similarly, FDA is not persuaded to make the requested change in proposed § 106.91(b). Proposed § 106.91(b) would establish testing requirements to ensure that the nutrients in infant formula products remain stable throughout the shelf-life of the products. The provisions of proposed § 106.91(b) implement section 412(b)(2)(B)(ii) of the FD&C Act. The reasons to conduct in-process and finished product testing to confirm the presence and levels of all nutrients apply to stability testing as well, a point not disputed by the comment. Thus, FDA is not revising § 106.91(b) in the interim final rule in response to this comment. Additional comments on proposed § 106.91(b) are addressed in this document.

(Comment 174) One comment suggested that proposed § 106.91(a)(4) be revised to state that each batch (production aggregate) of infant formula must be tested for all nutrients required to be included in such formula under § 107.100 "if the presence of that nutrient in the batch (production

aggregate) has not been confirmed pursuant to testing" conducted for compliance with § 106.91(a)(1) (premix testing) or (a)(3). The comment suggested substituting this language for that in the proposal to convey better that a manufacturer may rely on testing under § 106.91(a)(1) instead of requiring that finished product be retested for nutrients confirmed to be a part of a premix used in the infant formula. This comment also suggested that § 106.91(a)(2) (testing for an indicator nutrient for each nutrient premix) be added as another means of testing that would exclude the need to test for a nutrient under proposed § 106.91(a)(4). The comment stated that testing under § 106.91(a)(2) should be included in the list of prior testing recognized as a substitute for finished product testing because testing under proposed § 106.91(a)(1) would only confirm that a nutrient is present at the appropriate level in the premix and not establish that the nutrient is present at the appropriate level in the infant formula.

(Response) FDA is not persuaded by this comment to revise proposed § 106.91(a)(4). Section 106.91(a)(4) of the interim final rule parallels the statutory language of section 412(b)(3)(C) of the FD&C Act, which requires that each batch (production aggregate) of infant formula be tested for all required nutrients for which testing has not been conducted under sections 412(b)(3)(A) (final product stage testing) and 412(b)(3)(B) (premix testing) of the FD&C Act. Under proposed § 106.91(a)(4), a manufacturer is permitted to rely on testing under § 106.91(a)(1) (premix testing for relied upon nutrients) and thus, would not be required to test a production aggregate of finished infant formula for each relied upon nutrient that has been evaluated under § 106.91(a)(1), unless testing of the nutrient is also required at the final product stage by section 412(b)(3)(B) of the FD&C Act (i.e., vitamins A, C, E, and thiamin).

In addition, proposed § 106.91(a)(4) would already provide for an exemption for nutrients tested as indicator nutrients under proposed § 106.91(a)(2). Specifically, any indicator nutrient testing under proposed § 106.91(a)(2) would be conducted during the manufacturing process after the addition of the premix, or at the final product stage. If so tested, the manufacturer would have satisfied, for that indicator nutrient, the requirement in proposed § 106.91(a)(4). Therefore, if the nutrient used as the indicator nutrient in tests conducted under proposed § 106.91(a)(2) is a required or added nutrient, the manufacturer would have met testing requirements established for the nutrient under proposed § 106.91(a)(4). If the indicator nutrient is tested under proposed § 106.91(a)(2) and is also a nutrient that is required to be tested under proposed § 106.91(a)(1), the nutrient would need to be tested twice during manufacturing. However, as the comment recognizes, the nutrient testing under proposed § 106.91(a)(1) and (a)(2) have separate and distinct purposes and both types of testing are necessary to ensure that the infant formula contains the nutrients it is intended to contain.

On its own initiative, FDA is making minor editorial changes in § 106.91(a)(4) of the interim final rule and is also clarifying that the phrase "for which testing is not conducted for compliance with paragraphs (a)(1) or (a)(3) of this section" applies both to required nutrients and any nutrient not required but added by the manufacturer, except that the latter would not have been tested under § 106.91(a)(3) of the interim final rule.

2. Testing of Packaged Finished Product To Confirm the Presence of the Nutrients Required Under § 107.100 and Any Nutrients Added by the Manufacturer (Proposed § 106.91(b))

The Agency received a number of comments objecting to the stability testing requirements in proposed § 106.91(b). This proposed provision would implement section 412(b)(2)(B)(ii) of the FD&C Act, which was part of the 1986 amendments, and would revise and replace current § 106.30(b)(3). Proposed § 106.91(b) differs from the current stability analysis requirements in three principal ways: it would require the collection of representative samples every three months; it would require that stability testing of a formula assess all nutrients (both required and those added by the manufacturer); and it would expressly require that stability testing be performed on the collected samples at the beginning, the midpoint, and the end of the shelf life of the product. The 1996 preamble noted that quarterly testing of infant formulas for nutrient stability was the current practice of the industry and that FDA was not aware of any problems resulting from this frequency of testing. In addition, the Agency expressly requested comment on the appropriateness of the 3-month frequency for stability testing sample collection.

(Comment 175) One comment argued that proposed § 106.91(b) inappropriately combines requirements for periodic analyses and stability testing. The comment suggested establishing separate requirements for periodic analyses and stability testing because these two testing regimens serve different purposes. The comment explained that periodic analysis confirms on a quarterly basis the proper operation of the controls used by a manufacturer to ensure the presence of all required nutrients within required ranges in the finished infant formula. In contrast, the comment further explained, stability testing serves as a check that labeled nutrients present in the infant formula at the finished product stage do not, over the shelf life of the formula, degrade below minimum levels.

(Response) FDA believes that the comment results in part from the lack of clarity in proposed § 106.91, which did not separately identify requirements for periodic testing and stability testing. The Agency does, however, agree with the comment's description of the nature and purpose of stability testing and also agrees that one purpose of periodic testing can be to confirm the proper operation of the controls used by a manufacturer.

FDA has considered this comment and has carefully analyzed the various quality control testing requirements in proposed § 106.91. The Agency has concluded that the testing required by § 106.91(a) of the interim final rule can serve as final product testing of each production aggregate and also fulfill the purpose of periodic testing by serving as a check on the proper operation of the controls used by a manufacturer to ensure the presence and proper concentration of all nutrients. As discussed previously in this document, § 106.91(a)(1) of the interim final rule requires the manufacturer to test each premix before manufacture of an infant formula to ensure that each premix meets its specifications; § 106.91(a)(2) of the interim final rule requires the manufacturer to test, during the manufacture of the infant formula, after addition of the premix, or at the final product stage, for at least one indicator nutrient for each nutrient premix used in the infant formula to confirm that the appropriate amount of each premix is present in the production aggregate of infant formula; § 106.91(a)(3) of the interim final rule requires the manufacturer to test each production aggregate for the labile vitamins (vitamins A, C, E, and thiamin) at the final product stage, before distribution; and § 106.91(a)(4) of the interim final rule requires the manufacturer to test during the manufacturing process, or at the final product stage, each production aggregate for all nutrients required to be in the formula under § 107.100 of this

chapter and for any nutrient added by the manufacturer, for which testing was not conducted for compliance with paragraphs (a)(1) or (a)(3). When the manufacturer conducts these tests as required by § 106.91(a) of the interim final rule, the results will show whether all nutrients required under 21 CFR 107.100 and any other nutrient added by the manufacturer are present and at the proper concentration. These collective results can also be used to evaluate whether the manufacturer's production controls are functioning properly because any nutrient not identified in the production aggregate or not found at the correct concentration would be evidence that the production controls may not be functioning properly. In such circumstances, the manufacturer would need to address the production aggregate shown to be out of compliance and would also need to evaluate the production controls to determine where the error occurred. Because the testing in § 106.91(a) of the interim final rule not only confirms the presence and concentration of the nutrients in the particular production aggregate, but can also serve to demonstrate the proper functioning of the manufacturing controls, FDA concludes that specific requirements for periodic testing in § 106.91 of the interim final rule are not necessary.

(Comment 176) One comment suggested that periodic analysis requires that quarterly, a manufacturer test a finished batch (production aggregate) of each form of infant formula (from each facility) for all nutrients not analyzed directly in the immediate analysis of that batch (production aggregate).

(Response) As discussed in the response to the preceding comment, the Agency has determined that the testing requirements of § 106.91(a) of the interim final rule will satisfy the requirement in section 412(b)(2)(B)(iii) of the FD&C Act, which requires that the manufacturer test finished products to confirm that in-process controls (i.e., CGMP) are operating properly and thereby, are preventing the production of adulterated infant formula. That is, because § 106.91(a) of the interim final rule requires each production aggregate to be tested for the presence and level of all nutrients in the final formula product, testing conducted to satisfy § 106.91(a) of the interim final rule can also be used to determine whether a manufacturer's production controls are operating properly.

(Comment 177) One comment suggested permitting an appropriate sampling and testing program for infant formulas produced less frequently than every three months.

(Response) Because the interim final rule will not require periodic testing, no response to this comment is required. Importantly, however, an infant formula that is produced infrequently must still comply with the nutrient testing requirements of § 106.91(a) of the interim final rule and the stability testing requirements of § 106.91(b) of the interim final rule.

(Comment 178) Several comments argued that the stability testing requirements in proposed § 106.91(b) are excessive. One comment asserted that the proposed stability testing requirements require an excessive number of infant formulas and nutrients to be routinely analyzed and proposed that infant formula manufacturers continue to follow the requirements of the current § 106.30(b)(3), which requires a manufacturer to conduct a stability analysis, using representative samples collected from finished product batches (production aggregates), for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product.

(Response) The Agency disagrees that proposed § 106.91(b) would require an excessive number of infant formulas to be routinely tested. It is well-recognized that nutrient stability is affected by several factors, including the form of the infant formula (powder, ready-to-feed, or concentrate), the matrix of the formulation, processing techniques, and packaging (Ref. 61). Given the impact of these variables, it is scientifically sound to require that stability testing be performed on each production aggregate of each physical form (powder, ready-to-feed, or concentrate) of each infant formula from each manufacturing facility because different forms of the product may contain different ingredients, and the various forms of infant formula are subjected to manufacturing conditions and processing procedures that are specific to the product and to the manufacturing facility. As noted, each of these factors could affect the stability of the product.

The stability analysis required by the current regulation (21 CFR 106.30(b)(3)) is not adequate given the range of factors that are known to affect nutrient stability. For example, § 106.30(b)(3) requires analysis only for selected nutrients and does not specify the frequency of such testing to substantiate the maintenance of nutrient content throughout the shelf life of the product.

Therefore, it is entirely reasonable to require that stability testing include the analyses stipulated in proposed § 106.91(b). As explained in this document, the Agency is revising the proposed stability testing provisions to distinguish between the comprehensive stability testing of the first production aggregate of a new infant formula (§ 106.91(b)(1) of the interim final rule) and the routine stability testing of subsequent production aggregates of the same formula (§ 106.91(b)(2) of the interim final rule).

Specifically, under § 106.91(b)(1) of the interim final rule, the manufacturer must demonstrate the appropriateness of the proposed shelf life by completing the comprehensive testing of the first production aggregate of the new infant formula every three months during the proposed shelf-life and such testing must substantiate the shelf life established for the product. If the testing conducted under § 106.91(b)(1) of the interim final rule does not substantiate the chosen stability date, the manufacturer is required by § 106.91(b)(3) of the interim final rule to repeat the comprehensive stability testing under § 106.91(b)(1) of the interim final rule to confirm that the infant formula provides, throughout the shelf life of the infant formula, appropriate levels of both required nutrients and any nutrients added by the manufacturer. Alternatively, the manufacturer may choose to revise the shelf life date for the formula so that it is substantiated by the results of the comprehensive stability testing. Additionally, where the testing under § 106.91(b)(1) of the interim final rule fails to support the shelf life date, the manufacturer must take appropriate action with regard to any distributed formula bearing such unsubstantiated shelf life date.

In addition to comprehensive stability testing, the manufacturer is required by § 106.91(b)(2) of the interim final rule to conduct routine stability testing of each production aggregate of a formula at the beginning, midpoint, and end of its shelf life. If the results of this routine testing show that any required nutrient is not present in a production aggregate at the level required by § 107.100 or that any nutrient added by the manufacturer is not present at the level declared on the formula's label, the manufacturer must take steps to understand these results. Specifically, § 106.91(b)(4) of the interim final rule requires the manufacturer to investigate the cause of a variance in the level of any nutrient; to evaluate the significance of the results for other production aggregates of the same formula that have been released for distribution; to determine which production aggregates are implicated by the results and address those production aggregates as appropriate; and to determine whether

it is necessary to repeat the comprehensive stability testing required by § 106.91(b)(1) of the interim final rule.

(Comment 179) One comment suggested that stability "testing every three months for vitamins and minerals should be used only when a new product is introduced and until a history for that product is established. After 2 years of experience is acquired, then stability testing should be only at the beginning, middle, and end of shelf life."

(Response) FDA agrees in part with this comment. As such, § 106.91(b) of the interim final rule focuses on stability testing and differentiates between the initial comprehensive stability testing required for the first production aggregate of a new infant formula (§ 106.91(b)(1) of the interim final rule) and the routine stability testing of subsequent production aggregates of that new formula (§ 106.91(b)(2) of the interim final rule). For example, as applied to a new infant formula in liquid form first produced in January and initially labeled with a 1-year shelf life, the requirements of § 106.91(b) of the interim final rule would require testing in the following months: "First production aggregate: January, April, July, October, and December. Subsequent production aggregates: January, July, and December."

Thus, routine stability testing at the beginning, midpoint, and end of a product's shelf life should be retained for all formula products after the completion of the comprehensive stability testing of the initial production aggregate; these are the formulas with which the manufacturer has had previous experience. Stability testing at the beginning of the shelf life shows that the formula is in compliance with the nutrient requirements of the FD&C Act when it is released for distribution. (FDA notes that in some circumstances, the results from the testing required under § 106.91(a)(4) of the interim final rule could also be used to meet the requirements for initial stability testing of a particular production aggregate at the beginning of the shelf-life and thereby reduce duplicative analyses.) Testing at the end of the shelf life confirms that the formula contains all the nutrients needed to comply with the FD&C Act throughout its shelf life and will provide continued justification for the predicted shelf life. Testing at the midpoint of the shelf-life will provide an early indicator when nutrient concentrations are decreasing more rapidly than anticipated, based on previous experience.

(Comment 180) Another comment argued that the proposed level of quality control testing is appropriate for new infant formulas to guard against unexpected changes in the formula, but is inappropriate for an experienced infant formula manufacturer.

(Response) The Agency agrees with the comment to the extent that the comment suggests that a new infant formula, as defined in § 106.3 of the interim final rule, requires more frequent testing than products with which the manufacturer has experience, and § 106.91(b)(1) of the interim final rule reflects this principle. The 1986 amendments refer to "regularly scheduled testing." With respect to what constitutes "regularly scheduled testing" for each nutrient in the infant formula, the Agency agrees that the stability testing of the initial production aggregate of a "new infant formula" needs to be more frequent because the infant formula manufacturer will have had very limited or no experience with the stability of all nutrients in the particular formula matrix.

FDA emphasizes that it is important that the stability testing be conducted on the new infant formula product manufactured for the marketplace, i.e., the formulation, processing, and packaging of the marketed product. In the past, some infant formula manufacturers have used pilot production aggregates that differed from the marketed product in formulation, processing, or packaging to assess the stability of the product and to assign the shelf-life. For these reasons, the Agency is requiring that the first production aggregate of a "new infant formula," as defined in § 106.3 of the interim final rule, for distribution be tested every three months during its predicted shelf-life.

(Comment 181) Several comments objected to the stability testing requirements proposed in § 106.91(b)(2), which would require quality control testing of an infant formula that has been changed in formulation or in processing in a way that does not make it a new infant formula but that may affect whether it is adulterated under section 412(a) of the FD&C Act. These comments suggested that the manufacturers should determine whether stability testing needs to be conducted for such a change. One comment contended that quality control testing on changed infant formulas only needs to be conducted for each nutrient that has been or may have been significantly and adversely affected by the change.

(Response) FDA has considered these comments and has significantly revised proposed § 106.91(b)(2). Under § 106.91(b) of the interim final rule, a reformulated infant formula is subject to the comprehensive stability testing of § 106.91(b)(1) of the interim final rule only if the change in the formula causes the formula to be a "new infant formula" within the meaning of § 106.3 of the interim final rule. Utilizing the concept of a "new infant formula" is a reasonable basis for distinguishing when the comprehensive testing of § 106.91(b)(1) of the interim final rule and the routine testing of § 106.91(b)(2) of the interim final rule would be required. The Agency believes that this revision responds to the concern expressed by the comment.

(Comment 182) One comment stated that confirming the presence of a mineral throughout the formula product's shelf life is not necessary because minerals do not degrade.

(Response) FDA agrees that minerals do not undergo degradation and will remain stable throughout the shelf-life of an infant formula. Although it is critical to test for the presence and level of minerals in the finished product, as required by § 106.91(a) of the interim final rule, the Agency agrees that subsequent analysis as a part of stability testing for the presence and level of minerals is not needed because these ingredients do not degrade. Therefore, § 106.91(b)(5) of the interim final rule exempts all required minerals (calcium, phosphorus, magnesium, iron, iodine, zinc, copper, manganese, sodium, potassium, and chloride), as well as any mineral added to the formula by the manufacturer, from the requirements for stability testing in § 106.91(b)(1) and(b)(2) of the interim final rule.

(Comment 183) One comment suggested that the proposal be revised to require stability testing of only labile nutrients. (A labile nutrient is one that readily or frequently undergoes chemical or physical change.)

(Response) FDA does not agree that only labile nutrients should be the subject of stability testing as such approach would not address the concerns that resulted in the 1986 amendments.

Although section 412(b)(2)(B)(ii) of the FD&C Act, added by the 1986 amendments, does not specify which nutrients must be tested to ensure stability of the infant formula, the Agency proposed to require, under its authority to establish quality control procedures, that all nutrients be tested in a stability testing program. Infant formula is very often the sole source of nutrition for infants during a critical developmental period. As noted previously in this document, it is well

established that the absence or inappropriate amount of any of the nutrients listed in § 107.100 may cause adverse effects, many of which may be life-threatening or result in life-long impairments (Refs. 62, 63, 64, 65, and 66). Without testing for the stability of all nutrients, a manufacturer cannot know whether the level of a particular nutrient has declined. (As noted in the preceding comment, FDA recognizes that because minerals do not degrade, it is entirely reasonable that stability testing not extend to such substances.) Thus, it is both essential and reasonable to require stability testing of all nutrients, both required and added (except minerals), in an infant formula.

(Comment 184) One comment suggested that the title of proposed § 106.91(b) be changed from "Stability testing" to "Testing of packaged, finished product to confirm that the infant formula provides nutrients in accordance with sec. 107.100."

(Response) As noted, to make § 106.91 of the interim final rule consistent with the rest of part 106, FDA is deleting the titles from the paragraphs in this section, including § 106.91(b).

(Comment 185) Several comments stated that the manufacturer should determine the frequency of stability testing, if deemed necessary.

(Response) The Agency agrees in part with the comment that recommended that the manufacturer determine the frequency of stability testing. The Agency disagrees that the manufacturer should be allowed to test less frequently than required under § 106.91(b)(1) or (b)(2) of the interim final rule. The Agency views this testing frequency as the minimum required to ensure nutrient stability over the shelf-life of the product. However, if a manufacturer wishes to test more frequently than required under § 106.91(b)(1) or (b)(2) of the interim final rule, FDA would not object to additional testing by the manufacturer.

B. Audits of Quality Control Procedures (Proposed § 106.92)

In 1996, FDA proposed to require in § 106.92 that infant formula manufacturers conduct regularly scheduled audits of a firm's compliance with those quality control procedures that are necessary to ensure that a formula provides nutrients in accordance with section 412(b) and (i) of the FD&C Act, and is manufactured in a manner designed to prevent adulteration of the infant formula. Proposed § 106.92 would also have required that such audits be performed by a person with knowledge of all aspects of infant formula production and FDA's quality control regulations but who had no direct responsibility for the matters being audited. The Agency received several comments on proposed § 106.92, which are addressed in this document.

FDA notes that proposed § 106.90 (Audits of current good manufacturing practice) and proposed § 106.92 (Audits of quality control procedures) would have imposed similar requirements for the two types of audits. As a result, several comments FDA received addressed both proposed § 106.90 and proposed § 106.92. For this reason, the discussion that follows references the responses to certain comments on proposed § 106.90 (section V.N).

(Comment 186) One comment stated that requiring that the auditor be knowledgeable in "all" aspects of infant formula production is a lofty expectation given the complexities of an infant formula production environment. The comment suggested that the auditor should possess a general knowledge of the areas being audited, but not the depth and extent implied by the word "all."

(Response) As noted previously in this document in section V.N (Comment 165), FDA disagrees that the standard in proposed § 106.92(b) is a "lofty" expectation. As with any audit, to be valid and effective, the auditor must have well-developed knowledge of the focus of his audit. In this case, this means that the individual conducting the audit must have in-depth knowledge of infant formula production as well as the regulations governing that process. In responding to Comment 165, the Agency explained that using a team of individuals is a permissible approach to audits of infant formula manufacturing, and is one way that the necessary breadth of expertise can be assembled for an audit.

(Comment 187) Another comment agreed with the Agency that an auditor must not have direct responsibility for the matters being audited, but took exception to the preamble statement that the auditor must have no "past involvement in the activities being audited." The comment contended that this requirement presents a dilemma if the auditor must have knowledge of infant formula production, but could have no past involvement where knowledge might have been gained. The comment recommended that a reasonable time (1 year) be established after which any concern about potential bias would dissipate and an auditor could evaluate an area of previous employment.

(Response) As noted previously in this document in section V.N, in order to be meaningful and function as an appropriate oversight tool for quality control compliance, an audit, including one conducted under proposed § 106.92, must be as objective as possible although, as noted, the Agency is persuaded that there may be certain circumstances in which an auditor with prior involvement in the activities being audited could still perform an unbiased audit. In designating an individual to conduct an audit under § 106.92(b), the manufacturer should consider the factors identified in the response to Comment 166 and determine that the proposed auditor is able to be objective and to exercise independent judgment.

(Comment 188) One comment contended that firms would have to hire auditors from outside their company to perform audits since an individual could not audit his or her own area and it would be unlikely that one person would be knowledgeable in all areas of plant operations. The comment pointed out that hiring an outside auditor would be an added expense and suggested that auditing could be conducted as effectively by in-house auditors trained in auditing practices.

(Response) As discussed previously in this document in section V.N, FDA disagrees that a firm would have to hire auditors from outside its company to perform audits regardless of whether the audits are CGMP or quality control audits. First, section 412(b)(2)(B)(iv) of the FD&C Act would not preclude an auditor being an employee of the manufacturer. In addition, as noted, a manufacturer may utilize a team approach to ensure an audit is conducted by individuals, whether employees of the manufacturer or otherwise, with comprehensive knowledge of the infant formula production process and may also utilize an individual to audit an area of his/her prior responsibility so long as the manufacturer determines that an audit by such individual would be objective and free of bias. Thus, FDA disagrees that the audit provisions of proposed § 106.92 would require a manufacturer to hire individuals from outside the firm to conduct audits.

(Comment 189) One comment suggested that the language of proposed § 106.92 be changed to clarify that it is the manufacturer's responsibility to determine what will constitute "regularly scheduled audits" and to establish SOPs for that purpose. To achieve this goal, the comment suggested that proposed § 106.92 be revised to state that the manufacturer must conduct audits "according to its established practice."

(Response) FDA disagrees that proposed § 106.92 should be revised to make the established practice of the manufacturer the only basis for the conduct of "regularly scheduled" audits.

The 1986 amendments to section 412 of the FD&C Act reflect a Congressional determination that greater control over the formulation and production of infant formula was needed. A total quality control program for the manufacture of infant formula is necessary to ensure that each production aggregate of formula is uniform in composition and conforms to the nutrient requirements for infants. Under section 412(b)(2)(B)(iv) of the FD&C Act, a manufacturer is required to conduct audits at regularly scheduled intervals. Thus, in response to this comment, FDA advises that "regularly scheduled" means that a manufacturer shall conduct, at each manufacturing facility, audits at a frequency that is required to ensure compliance with such regulations, with additional audits as needed, to determine whether the manufacturer has complied with the quality control procedures regulations.

For clarity, FDA is dividing proposed § 106.92 into two sections. Section 106.92(a) of the interim final rule establishes the regularly scheduled audit requirement, and § 106.92(b) of the interim final rule establishes the audit personnel requirement.

VII. Subpart D—Conduct of Audits

Audit Plans and Procedures (Proposed § 106.94)

Three separate sections of the interim final rule address audits. Section 106.90 of the interim final rule establishes the requirement to conduct audits of compliance with CGMP, and § 106.92 of the interim final rule establishes the requirement to conduct audits of compliance with quality control procedures. These provisions both implement section 412(b)(2)(B)(iv) of the FD&C Act. Subpart D (§ 106.94 of the interim final rule) establishes requirements for audit plans and procedures.

In the 1996 proposal, FDA proposed in § 106.94 to require that infant formula manufacturers develop and follow a written audit plan. The audit plan would be required to set out the method used to determine whether the firm is operating in compliance with CGMP, including quality control procedures, and would include evaluation of the firm's production and in-process controls, a comparison of the written plan to the observed process, and review of certain records, including monitoring records, specification deviation investigations, and a representative sample of all records maintained under proposed § 106.100(e) and (f).

The Agency received comments on several aspects of § 106.94, which are addressed in this document. Although FDA declines to make any of the revisions to subpart D in response to the comments received, the Agency is making minor editorial revisions in this subpart.

(Comment 190) One comment objected to proposed § 106.94(c)(1)(i) which would require observation of the production of infant formula and comparison of the observed process to the written production and in-process control plan. The comment stated that this proposal could be interpreted as requiring observation of every single manufacturing operation, from ingredient receipt through manufacturing, holding, and distribution, and that such detail during an audit would make the auditing process an extremely tedious and unwieldy endeavor and would result in overly prolonged audits. The comment proposed that the actual observation portion of the audit be devoted to the critical, product/line specific steps of the process as defined by the manufacturer.

(Response) FDA disagrees with this comment. The requirement that a manufacturer conduct regularly scheduled audits to assess compliance with CGMP, including quality control procedures, derives from section 412(b)(2)(B)(iv) of the FD&C Act, which mandates that CGMP and quality control procedures regulations include requirements for regularly scheduled audits by a formula manufacturer to determine whether the manufacturer has complied with such regulations. Thus, the scope of a manufacturer's audits, and the audit plans and procedures established under proposed § 106.94(c)(1)(i), is determined by the breadth of the CGMP and quality control procedure requirements. Section 106.6(a) of the interim final rule requires a manufacturer to establish a system of production and in-process controls that covers all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product, and § 106.6(b) of the interim final rule requires a written plan of such system. To assess compliance adequately, an audit must extend to all of these areas of production. Thus, it is appropriate that the audit plan required under proposed § 106.94(c)(1)(i) include observation of each element of the manufacturing operation, from ingredient receipt through manufacturing, holding, and distribution. Accordingly, FDA is not revising § 106.94(c)(1)(i) in the interim final rule in response to this comment.

(Comment 191) One comment claimed that proposed § 106.94(c)(1)(i) would require additional trained personnel to complete this type of audit, and that this requirement would interfere unnecessarily with the focus on high quality production.

(Response) FDA notes that this comment did not explain its assertion that additional personnel would be required to complete an audit under proposed § 106.94(c)(1)(i). Nor did the comment explain how this proposed requirement would interfere with high quality production. Without such details, FDA cannot respond to the comment. Moreover, in its response to comments on the requirement to conduct audits of compliance with CGMP and compliance with quality control procedures, FDA addressed similar comments about the need for additional trained personnel to conduct the audits that would be required by proposed §§ 106.90 and 106.92. In short, the audit provisions (proposed §§ 106.90. 106.92, and 106.94) provide ample flexibility in terms of audit personnel.

For the foregoing reasons, § 106.94(c)(1)(i) is included in this interim final rule as proposed.

(Comment 192) One comment suggested revising proposed § 106.94(c)(1)(ii), which requires that the audit procedures include reviewing records of the monitoring of points, steps, or stages where control is necessary to prevent adulteration. The comment noted that the 1996 preamble to this proposed section stated that the review of "production and in-process control records" contemplated by this section must involve "all batches produced in a given period of time" (61 FR 36154 at 36178). The comment recommended that the required audit procedures be revised to include a review of records of representative batches, over multiple days of production, of the monitoring of points, steps, or stages where control is critical to prevent adulteration, asserting that such audits would be more thorough and beneficial if the records reviewed covered a wider span of time (i.e., months), but extended only to "representative" batches, not "all" batches, and to "representative" records of only the most important control points (i.e., "critical points").

(Response) As discussed in this document, FDA declines to make the revisions requested in this comment.

The purpose of an audit is to identify conditions related to production and in-process controls that may result in the manufacture of an adulterated infant formula. The Agency agrees with the comment that an effective production and in-process control system audit may be based on a "representative sample" (as defined in § 106.3), of production aggregates covering several months, and proposed § 106.94 provides flexibility to the manufacturer as to the period of production specified for review in the manufacturer's audit plan. Importantly, however, the audit plan developed by the manufacturer under proposed § 106.94 must ensure that the audit covers a sufficient number of products over a sufficient period of time so that the manufacturer is able to determine whether its operations are in compliance with CGMP, including quality control procedures required by this interim final rule, to ensure that its infant formula provides the required and added nutrients at the appropriate levels and is manufactured in a manner designed to prevent adulteration. The audit plan should provide a reasonable probability that any discrepancies in the process can be identified. The audit plan must also provide a mechanism whereby the manufacturer can identify any production practices or in-process controls that require revision to ensure compliance with all requirements for infant formula. FDA disagrees, however, with the comment to the extent that it asserts that an audit should be limited to "representative records of the most important control points." As discussed in the response to Comment 190, an effective audit must be co-extensive with the production and in-process controls established under § 106.6 of the interim final rule. Similarly, in order for such audit to be effective, an audit must extend to the records of all points, steps, or stages where control is necessary to prevent adulteration for each production aggregate in the representative sample of an infant formula audited.

Importantly, under § 106.6 of the interim final rule, a manufacturer has both the responsibility and the flexibility to identify in its own production process those points, steps, or stages in the process where control is necessary to prevent adulteration of formula. Any point, step, or stage identified by the manufacturer as a focus for control under § 106.6 of the interim final rule is, by definition, "critical" to producing an infant formula that is not adulterated. Thus, it is essential that all of these points, steps, or production stages be audited, including through a review of the records related to such points, steps, or production stages, to confirm that the relevant controls are functioning properly and ensuring that no adulterated formula is produced. Moreover, as noted previously in this document, audits by infant formula manufacturers are required by section 412(b)(2)(B)(iv) of the FD&C Act, and a requirement that a manufacturer's audits be limited to a review of the "most important control points" would not allow a manufacturer to determine whether it has complied with the CGMP, including quality control procedures, regulations as mandated by section 412(b)(2)(B)(iv) of the FD&C Act. Thus, it is entirely appropriate that the audit plan established under § 106.94(c) of the interim final rule require the review of the records relating to all of the points, steps, or stages of the production process where control is deemed necessary to prevent adulteration.

For these reasons, FDA declines to revise proposed § 106.94(c)(1)(ii), and this provision is included in this interim final rule as proposed.

(Comment 193) One comment suggested that proposed § 106.94(c)(1)(iii), which would require reviewing records of the handling of deviations from any standard or specification at points, steps, or stages where control is deemed necessary to prevent adulteration should be revised by adding the phrase "to assure that the review was complete." The comment noted that the 1996 preamble states that the auditor must review these records to determine "whether the conclusions and follow-up of these investigations are appropriate for each failure to meet the specification or standard" (61 FR 36154 at 36178), and asserted that it is unrealistic to expect an auditor to have the background and breadth of technical knowledge to assess whether the dispositions were "appropriate." The comment claimed that such disposition decisions may involve multiple disciplines in a company, and it would be more reasonable to expect the auditor's review to confirm the completeness and sufficiency of such investigations, rather than to expect the auditor to determine whether the conclusions and follow-up were appropriate.

(Response) Although FDA agrees that an audit should confirm the completeness and sufficiency of the review of deviations from any standard or specification, this action would not fulfill all of the purposes of an audit. Because an audit serves as a manufacturer's follow-up mechanism to provide independent evaluation of a firm's management of deviations from specifications, a comprehensive audit must also include an evaluation of how the manufacturer responded to any deviation and whether the disposition decision was appropriate.

In terms of the comment's concern that an auditor may not have the requisite expertise to evaluate the response and disposition to a deviation, the Agency clarified in the response to Comment 165 that audits may be conducted by a single individual or by a team of individuals, each qualified to evaluate a particular portion or portions of the production process. In fact, the use of a team for audits is one way to ensure that an audit is comprehensive. Thus, proposed § 106.94(c)(iii) is not unrealistic and FDA is not persuaded to make the revision suggested by this comment.

(Comment 194) One comment objected to the requirement in proposed § 106.94(c)(1)(iii) that the review of all deviations from the manufacturer's standards or specifications at points, steps, or stages where control is necessary to prevent adulteration be a part of regularly scheduled audits. The comment suggested that instead of requiring the auditor to review all deviations, review of a random sample of deviations should be sufficient.

(Response) FDA disagrees that review of a "random sample" of deviations from a manufacturer's specifications would constitute a sufficient audit. The purpose of a quality control audit is to identify recurring problems and detect any weaknesses or flaws in the system. In order to maximize the likelihood of identifying a pattern of repeated failures, an audit must include the review of all deviations from specifications. As discussed previously in this document, the fact that a manufacturer fails to meet a specification requires prompt investigation to determine whether the manufacturing process is under control. A subsequent audit evaluates the handling of all such occurrences and assesses whether the appropriate material disposition decisions were made. Thus, a review of all deviations as a part of the audit will identify failures that occur and show how these failures are handled by the manufacturer.

For these reasons, FDA is not revising proposed § 106.94(c)(1)(iii) in response to this comment, and, with the exception of minor editorial revisions, § 106.94(c)(i)(iii) is included in this interim final rule as proposed.

VIII. Subpart E—Quality Factors

In Subpart E, "Quality Factors," comments often referred to both proposed § 106.96 and proposed § 106.97 because the subjects of these two proposed provisions are closely related. The interim final rule reorganizes and consolidates into a single section (§ 106.96 of the interim final rule) most of the content of proposed § 106.96 and proposed § 106.97 related to requirements for infant formula quality factors. In addition, § 106.121 of the interim final rule, which is discussed in section X.D., specifies the assurances for the established quality factors that a manufacturer is required to submit in a new infant formula submission or in a submission made under section 412(d)(3) of the FD&C Act. For these reasons, this portion of the preamble is generally organized by topic rather than by section of the proposed codified.

FDA notes that the Agency received several comments in response to proposed § 106.96 and § 106.97 that raised issues beyond the scope of this rulemaking. In particular, FDA received comments expressing concern about the safety of particular ingredients used in infant formula. Because the safety of particular infant formula ingredients is not at issue in this rulemaking, FDA is not responding to these comments.

A. Quality Factors: Legal Authority

Section 412(b)(1) of the FD&C Act, which was added to the statute by the 1986 amendments, requires that the Secretary ". . . establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i)."

Section 412(a)(2) of the FD&C Act deems an infant formula that does not meet the quality factors requirements established by the Secretary to be adulterated.

(Comment 195) One comment asserted that there is no basis in the plain language of the statute or in its legislative history to support an interpretation of "normal growth" as a quality factor, which would establish a requirement that applies to the infant formula as a whole. The comment cited to legislative statements and FDA testimony concerning the Infant Formula Act or the 1986 amendments to the Infant Formula Act as support for its assertion that Congress intended quality factors to be limited to individual components in the infant formula, and that the Infant Formula Act does not authorize FDA to require clinical studies for new infant formulas, including those that have undergone a major change.[7]

(Response) FDA disagrees with the suggestion that the Infant Formula Act does not support an interpretation of "normal growth" as a quality factor, or does not provide authority to require a well-controlled growth monitoring study to ensure that a formula will support normal physical growth. Such reasoning is flawed. Legislative silence on an issue is not persuasive when determining the meaning of a statute. *Central Bank* v. *First Interstate Bank,* 511 U.S. 164, 187 (1994) (stating that "Congressional inaction lacks persuasive significance"). Clearly, just as Congress is not expected to express "every single evil sought to be corrected" in a grant of authority to issue a rule, it cannot be expected to articulate every requirement that is within an Agency's delegated authority. *American Trucking Assoc.* v. *United States,* 344 U.S. 298, 309–10 (1953).

In addition, the various legislative statements and Agency testimony that the comment cites to support its assertion as to the meaning of "quality factors" are not on point. First, the congressional statements the comment cites to support its assertion that FDA lacks the authority to require testing of the infant formula as a whole (see footnote 1) discuss testing in the context of laboratory analysis of required nutrients; the statements in question do not relate to quality factors. Additionally, the Agency testimony cited by the comment, stating that Congress did not intend the use of clinical testing, comes from a discussion of the Infant Formula Act's *recall* provisions. Second, even if these congressional statements and FDA testimony were relevant, such isolated statements are not sufficient evidence of congressional intent. *See Weinberger* v. *Rossi,* 456 U.S. 25, 34–35 (U.S. 1982) (rejecting the argument that a single statement of a sponsor taken out of context should be determinative of congressional intent); *Regan* v. *Wald,* 468 U.S. 222, 237 (1984) (explaining that testimony of Senators and Representatives and witnesses can seldom be expected to be as precise as the language of the enacted bill, and should not later be permitted to undermine the bill).

FDA disagrees that there is no basis under the infant formula provisions of the FD&C Act to require a well-controlled growth monitoring study that demonstrates normal physical growth. Under section 412(a) of the FD&C Act, Congress stipulated that infant formula "shall be deemed to be adulterated if . . . such infant formula does not meet the quality factor requirements prescribed by the Secretary . . . ." Section 412(b)(1) of the FD&C Act further provides that "[t]he Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i)."

In construing the meaning of the term "quality factors," FDA is confronted with two questions. First, has Congress directly and unambiguously spoken to the precise question at issue ("*Chevron* step one") *Chevron U.S.A. Inc.* v.*Natural Resources Defense Council,* 467 U.S. 837, 842 (1984)? To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. See *Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the Agency must implement Congress's unambiguously expressed intent. *Chevron,* 467 U.S. at 842–843.

Second, if the FD&C Act is silent or ambiguous with respect to the meaning of "quality factors" in section 412(b)(1) of the FD&C Act, is the Agency's interpretation based on a permissible construction of the statute ("*Chevron* step two") *Chevron,* 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000)? When, as is the case here, Congress leaves a gap for the Agency to fill by regulation, the regulation will pass muster so long as it is not "arbitrary, capricious, or manifestly contrary to the statute." *Chevron,* 467 U.S. at 844.

The language in section 412(b)(1) of the FD&C Act provides an express delegation of authority to "by regulation establish requirements for quality factors for infant formulas to the extent

[7] The comment cites to floor statements in the Senate Record that describe the 1986 amendments as providing testing for "each essential nutrient" and as further describing "the quality factor of nutrient content requirements of the law, as demonstrated by the testing called for in the amendments." 132 Cong. Rec. S26775, 26777 (daily ed. Sept. 27, 1986). The comment also cites to a statement by then Commissioner of Food and Drugs Jere E. Goyan stating that the proposed legislation required "tests, including clinical tests, where appropriate." *See Nutritional Quality of Infant Formula: Hearings on H.R. 6590, H.R. 6608, H.R. 5836, and H.R. 5839 Before the Subcomm. on Health and the Environment of the H. Comm. on Interstate and Foreign Commerce,* 96 Cong. 132, 74 (1980). The comment notes that this statement by Commissioner Goyan was responded to by Representative Mottl, who replied that "I am speaking of analysis in the chemical and nutritional laboratories, and I am not referring to clinical trials." Id. at 120.

possible consistent with current scientific knowledge." This language necessarily contemplates broad Agency discretion to define the requirements for "quality factors," limited by current scientific knowledge.

Congress also spoke to the precise question of whether "quality factors requirements" were limited in application to the individual nutrients required to be in the formula under section 412(i) of the FD&C Act. Congress did not expressly limit quality factors in this way. Rather, the statutory language describing what requirements for quality factors are to be established states that the Secretary shall by regulation establish "quality factors for infant formulas . . . including quality factor requirements for the nutrients required by subsection (i)." The use of the word "including" demonstrates that Congress did not intend to limit quality factors for infant formulas to the nutrients in subsection (i). *See* Norman J. Singer & J.D. Shambie Singer, 2A Sutherland Statutory Construction § 47:7 (7th ed. 2009) (explaining that when a statutory definition declares what it "includes," it "conveys the conclusion that there are other items includable, though not specifically enumerated"); Eric C. Surrette et. al., American Jurisprudence § 130 (2nd ed. 2008) (explaining that "a statutory definition of a term as 'including' certain things does not necessarily put a meaning thereon limited to the inclusion"); *Gray* v. *Powell,* 314 U.S. 402 (1941) (explaining that "[t]he definition of disposal as including 'consumption or use by a producer, and any transfer of title by the producer other than by sale' cannot be said to put a meaning on disposal limited to the inclusion."); *Herb's Welding* v. *Gray,* 470 U.S. 414, 415, n. 9 (1985) (noting that by use of the term "including," Congress indicated that the occupations specifically mentioned in the law are not exhaustive). In sum, the infant formula provisions of the FD&C Act direct the Agency to establish quality factor requirements for infant formulas to the extent possible consistent with current scientific knowledge, without limitation to requirements relating only to the nutrients specified by statute to be included in all infant formulas. Congress did not, however, define the term "quality factors," nor did it describe what such quality factors might be. Instead Congress left a gap for the Agency to fill by regulation.

Because Congress left a gap for the Agency to define the term "quality factors" and determine what quality factor requirements are consistent with current scientific knowledge, under *Chevron* step two, FDA may define the term and determine what quality factor requirements may be imposed, provided that FDA's interpretation is not arbitrary, capricious, or manifestly contrary to the statute. *Chevron*, 467 U.S. at 844. Accordingly, when defining quality factors, FDA should consider the language itself, the placement of the language in the infant formula provisions of the FD&C Act, and other tools of statutory construction, including the purpose and the legislative history of the Infant Formula Act and the 1986 Amendments, as well as the FD&C Act. *See Barnhart* v. *Peabody Coal Co.*, 537 U.S. 149, 160 (2003) (looking to structure, purpose, and legislative history to interpret the Coal Act); *see also Chevron*, 467 U.S. at 843 (noting that if a statute is silent with respect to an issue the Agency's answer to the issue should be based on a permissible interpretation of the statute).

The language in the infant formula provisions of the FD&C Act does not define "quality factors," but it does define the scope of authority that Congress left FDA to establish quality factor requirements. As noted previously in this document, according to the language in section 412(b)(1) of the FD&C Act, quality factors include requirements related to nutrients in section 412(i) of the FD&C Act, but are not limited to such nutrients. This statutory language indicates that the Secretary must establish quality factors for (1) the individual nutrient components required under subsection (i), and, (2) the infant formula as a whole to the extent possible consistent with current scientific knowledge. If Congress had intended quality factors to be limited to individual nutrient components of the formula, such as protein and other nutrients that are added to the formula, Congress would not have needed to incorporate the "including" language referencing nutrients required by subsection (i).

The organization of section 412 of the FD&C Act aids in interpreting the intended meaning of quality factors. The statutory provisions for quality factor requirements are separate and distinct from the provisions for requirements related to CGMP and quality control procedures in section 412(b)(2)(A) and (b)(2)(B) of the FD&C Act. The placement of quality factor requirements in a separate statutory provision means that such requirements pertain to something other than the CGMP and quality control provisions that, in part, ensure that particular nutrients are present at particular levels in each production aggregate of infant formula. The preamble to the proposed rule recognized that quality control procedures and quality factor requirements are separate and distinct: "While quality control procedures are intended to ensure that the safety and nutritional potency of a formula is built into the manufacturing process," quality factors are "intended to ensure that an infant formula contains an adequate amount of each nutrient in a form that can be digested, absorbed, and utilized so that the infant's physiological needs for these nutrients will be met" (61 FR 36154 at 36179). Thus, the quality factors pertain not to a measurement of the amount of each nutrient in the formula, but to a broader concept of bioavailability; an infant formula as a whole and the individual nutrients in the infant formula must meet the physiological needs of infants when fed the formula as a sole source of nutrition to foster normal growth and development. As noted previously in this document, under the language of section 412 of the FD&C Act, Congress required the Secretary to establish quality factors for the infant formula as a whole as well as for individual nutrients to the extent that is consistent with current scientific knowledge. Thus, interpreting the infant formula provisions of the FD&C Act to mean that quality factor requirements that apply to the infant formula as a whole would pertain to the ability of the formula (i.e., all the nutrients in combination) to meet an infant's physiological needs, is reasonable. The quality factor of "normal physical growth" is designed to demonstrate the ability of the infant formula as a whole to meet such physiological needs.

Establishing normal physical growth as a quality factor requirement is consistent with the overall purpose of the Infant Formula Act. The need for an Infant Formula Act was discussed in the wake of the marketing of two infant formulas that "were critically deficient in chloride, a life sustaining nutrient." S. Rep. No. 96–359, at 3 (1980). The Infant Formula Act was meant to provide the Secretary with the means to ensure that formula "will promote healthy growth" in infants. H.R. Rep. No. 96–936, at 3 (1980). "Normal physical growth" is an essential component of "healthy growth," thus a quality factor requirement for the demonstration of normal physical growth is consistent with the overall purpose of the Infant Formula Act. Additionally, a report from the House Committee on Interstate Commerce that accompanied the Infant Formula Act supports the view that, as originally

enacted, the Infant Formula Act authorizes the establishment of quality factor requirements for normal physical growth. The report states: "Quality factors pertain to the bioavailability of the nutrient . . . ." H.R. 96–936, at 6 (1980).

In the 1986 amendments to the Infant Formula Act Congress clarified that quality factor requirements demonstrating the "bioavailability of the nutrient" referred to all nutrients combined in a formula as well as to individual nutrients. *See* 21 U.S.C. 350a(b)(1). The Infant Formula Act stated that the Secretary may by regulation "establish requirements for quality factors for such nutrients [required by subsection (g)]." Infant Formula Act of 1980, Public Law 96–359, § 2, 94 Stat. 1190 (1980). In 1986, however, the infant formula provisions were amended to specify in revised section 412(b)(1) of the FD&C Act that the "Secretary *shall* by regulation establish requirements for quality factors for infant formulas, . . . including quality factor requirements for the nutrients required by subsection (i)." (Emphasis added). This amendment clarified that quality factor requirements applied to the "infant formula" as a whole as well as to the individual nutrients required by subsection (i), and also made the establishment of requirements for quality factors mandatory.

Additionally, normal physical growth is an appropriate means to assess whether the infant formula as a whole meets the physiological needs of infants. Infants frequently consume formula as the sole or primary source of nutrition at a time when the requirements for nutrients are higher per kilogram body weight than at any other time during the life cycle. The net effect for an infant who consumes an infant formula that provides required nutrients in a bioavailable form is the ability of the infant to achieve normal physical growth. Normal physical growth is an indicator that an infant is thriving and is inextricably linked to the bioavailability of nutrients in an infant formula as a whole. Normal physical growth is an "integrative indicator of the net effect of the overall nutritional quality of the formula" (61 FR 36154 at 36180). Additionally, anthropometric measurements of length, weight, and head circumference are easily made, familiar to health care professionals, and are the same measurements as those done during routine office visits and for which standardized growth charts are available for comparison. Also, there is a very large amount of data available on what constitutes "normal physical growth." Thus, it is reasonable for the Agency to require the conduct of a well-controlled growth monitoring study, when necessary, to determine whether an infant formula meets the quality factor of normal physical growth.

Further, requiring such a study is reasonable when considering the statutory scheme as a whole. *See Brown & Williamson,* 529 U.S. at 133 (explaining that the words of a statute must be read in the context of the overall statutory scheme). FDA's explicit statutory mission is, in part, to protect the public health by ensuring that foods (including infant formula) are safe, wholesome, sanitary, and properly labeled (section 903(b)(2)(A) of the FD&C Act) (21 U.S.C. 393(b)(2)(A)). Further, the FD&C Act touches "phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich,* 320 U.S. 277, 281 (1943); see also *United States* v. *Park,* 421 U.S. 658, 668 (1975). The Infant Formula Act and the 1986 amendments were meant to ensure the "safety and nutrition" of infant formulas, a purpose achieved, in part, by growth monitoring studies. *See* Infant Formula Act of 1980, Public Law 96–359, 94 Stat. 1190, 1190 (1980) (prior to 1986 amendment).

Section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act in order to "effectuate a congressional objective expressed elsewhere in the Act" (*Association of American, Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Supp. 1179, 1183 (D. Del. 1980)). The validity of such regulations issued under section 701(a) of the FD&C Act is determined by a consideration of the "statutory purpose" of the FD&C Act, as well as an "understanding of what types of enforcement problems are encountered by the FDA [and] the need for various sorts of supervision to effectuate the goals of the Act." *National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693 (D.C. Cir 1978) (*citing Toilet Goods Ass'n* v. *Gardner,* 387 U.S. 158, 163–64); *see also Association of American Physicians and Surgeons, Inc.*, 226 F. Supp. 2d at 213; *NVE Inc.* v. *HHS,* 436 F.3d 182, 186–190 (3d Cir. 2006) (noting that section 701(a) of the FD&C Act grants FDA broad discretion to issue regulations for the efficient enforcement of the FD&C Act within the scope of the authority granted to it by Congress).

The interim final rule falls within FDA's discretion to issue regulations for the efficient enforcement of the FD&C Act. The interim final rule is designed, in part, to help ensure that infant formulas, when fed as a sole source of nutrition, will support normal physical growth in infants consuming the formula. The requirement to conduct a well-controlled growth monitoring study is designed to determine whether normal physical growth may be achieved using a particular infant formula. Such a study is consistent with the purpose of the Infant Formula Act, because it provides a mechanism by which FDA can determine whether the formula promotes one of the factors contributing to healthy growth (i.e., normal physical growth). *See* H.R. Rep. No. 96–936, at 3 (1980). The requirement to conduct such a study is written to facilitate efficient and effective action to enforce the FD&C Act's terms when necessary. The requirement to conduct a well-controlled growth monitoring study is also consistent with FDA's overall mission, because the study helps to ensure that the formula is safe and wholesome. (See section 903(b)(2)(A) of the FD&C Act (21 U.S.C. 393(b)(2)(A))).

FDA acknowledges that a well-controlled growth monitoring study may not be necessary to demonstrate normal physical growth for every new infant formula, including a change to a marketed formula that results in a new infant formula. Thus, FDA has included in the interim final rule exemptions from the requirement to conduct a well-controlled growth monitoring study for certain changes in processing or methods and, in addition, an opportunity for a manufacturer to demonstrate that an alternative study design or method would provide assurances that an infant formula supports normal physical growth or that a change to a formula that has already been shown to meet the quality factor requirements does not affect the bioavailability of the new formula, including its nutrients. In addition, it is reasonable and necessary for efficient enforcement of the FD&C Act for FDA to require that a manufacturer make and retain records demonstrating that the formula meets the quality factor of normal physical growth, and that certain records related to the requirement to conduct a growth monitoring study be included in the submission required in section 412(c)(1)(B) of the FD&C Act (21 U.S.C. 350a(c)(1)(B)). Under section 412(d)(1)(C) of the FD&C Act (21 U.S.C.

350(d)(1)(C)), assurances that the requirements for quality factors have been met must be provided in a submission. FDA is requiring that the assurances related to the quality factor requirements in the submission be included in the form of a record that FDA can review prior to the marketing of the infant formula to determine whether the infant formula is adulterated under section 412(a)(2) of the FD&C Act. Without records, FDA would not be able to evaluate whether an infant formula meets the quality factor requirements, such as normal physical growth.

For example, when a growth monitoring study is required, FDA needs certain data and information to evaluate the growth of the study participants (infants) who have been fed the infant formula under study. As discussed in this document, § 106.96(d) of the interim final rule requires manufacturers to make records demonstrating that the formula meets the quality factor of normal physical growth. Additionally, § 106.121 of the interim final rule requires a manufacturer to submit certain data and information that are required to be collected during the growth monitoring study and that are necessary to assess whether the infant formula supports normal physical growth. These data include all measurements for each feeding group at the beginning of the study, and at every point where measurements were made throughout the study. Without these data, and other data and information, FDA would not be able to assess whether the formula supports normal physical growth.

For the reasons stated previously in this document, it is reasonable and appropriate under *Chevron* for the FDA to establish normal physical growth as a quality factor requirement for infant formula. Further, it is reasonable to include a requirement to conduct a well-controlled growth monitoring study to evaluate whether an infant formula complies with the quality factor requirement of normal physical growth, and to require records related to such requirement.

B. Quality Factors for Infant Formulas

Section 106.96 of the 1996 proposed rule identified two infant formula quality factors: All infant formulas must be capable of supporting infants' normal physical growth and all infant formulas must be formulated and manufactured to ensure that the protein is of sufficient biological quality to satisfy infants' protein requirements. The term "quality factors" was defined in proposed § 106.3(o) as ". . . those factors necessary to demonstrate that the infant formula, as prepared for market, provides nutrients in a form that is bioavailable and safe as shown by evidence that demonstrates that the formula supports healthy growth when fed as a sole source of nutrition." In the preamble to the 1996 proposed rule (61 FR at 36179), FDA explained that "healthy growth" is a broad concept, encompassing all aspects of physical growth and normal maturational development, including maturation of organ systems and achievement of normal functional development of motor, neurocognitive, and immune systems. All of these growth and maturational developmental processes are major determinants of an infant's ability to achieve his/her biological potential, and all can be affected by the nutritional status of an infant.

To determine whether a formula supports normal physical growth in infants when fed as the sole source of nutrition, proposed § 106.97(a) would have required a formula manufacturer to conduct an "adequate and well-controlled clinical study." Proposed § 106.97(b) would also have required a formula manufacturer to collect and maintain data to demonstrate that the biological quality of a formula's protein is sufficient to meet the needs of infants.

As discussed in more detail in this document, in both the 2003 and 2006 reopenings, several issues related to requirements for quality factors were identified for additional comment. In response to comments and on its own initiative, FDA is reorganizing and consolidating into § 106.96 of the interim final rule most of the content of proposed §§ 106.96 and 106.97 related to requirements for infant formula quality factors.

C. Quality Factor: Normal Physical Growth

In 1996, FDA proposed (§ 106.96(b)) "normal physical growth" as a quality factor for infant formula and stated that such growth is a necessary indicator of the overall nutritional quality of a formula. The Agency's proposal was consistent with the view of the Committee on Nutrition of the American Academy of Pediatrics (CON/AAP) that the determination of physical growth is the most valuable component of the clinical evaluation of an infant formula (Ref. 67). FDA noted that physical measures of growth (e.g., weight gain) are a widely accepted measure of an infant's overall ability to utilize a formula's nutrients, are familiar to practitioners and parents, are readily made, and are not invasive.

In the 2003 reopening, the Agency expressly requested comment on the two quality factors that it had tentatively identified in the 1996 proposal: Normal physical growth and protein biological quality. In particular, FDA requested comment on the appropriateness of these quality factors and any information on other quality factors that could be implemented consistent with current scientific knowledge, as required under section 412(b)(1) of the FD&C Act.

This interim final rule establishes as part of § 106.96(a) the general quality factor of "normal physical growth." (As discussed in section IV. C., the proposed definition of "quality factors" has been slightly revised in § 106.3.) FDA considered comments received from the public, as discussed in this document, when including "normal physical growth" as one quality factor.

(Comment 196) Several comments supported FDA's proposal to designate "normal physical growth" as a quality factor for all non-exempt infant formulas. One comment stated that overall physical growth and protein quality are reasonable benchmarks, assuming that the formula contains all nutrients required by law.

(Response) FDA agrees with the comments that support the establishment of "normal physical growth" and "protein quality" as infant formula quality factors. In considering the provision for "normal physical growth," the Agency notes the IOM's conclusion (Ref. 4, p. 105): "Growth is well recognized as a sensitive, but nonspecific, indicator of the overall health and nutritional status of an infant. Monitoring infant growth has always been an integral part of pediatric care and is particularly important for young infants."

(Comment 197) Another comment agreed that growth is clearly an indicator of bioavailability but nonetheless challenged the Agency's proposal to define "normal physical growth" as a quality factor, asserting that few changes in an infant formula raise bioavailability questions and objecting to the routine demonstration of growth relative to most changes in an infant formula.

(Response) FDA disagrees with this comment for two reasons. First, the comment does not dispute—indeed, agrees—that growth is a clear indicator of formula bioavailability. Thus, the comment does not erode or otherwise undermine FDA's rationale for defining "normal physical growth" as a quality factor for infant formula. Second, although the comment asserts that few changes in infant formulas create

bioavailability issues, the comment provided no data or other information to support this assertion. The Agency notes that, among others, the IOM has recognized that infant formula matrix changes can highly influence nutrient bioavailability (Ref. 4, p. 45). In addition, the interim final rule provides an exemption for new infant formulas from the requirements for a growth monitoring study in § 106.96(b), if the formula manufacturer provides assurances that demonstrate that the change made to the existing formula does not affect the bioavailability of the formula, including the nutrients in such formula.

Accordingly, the interim final rule establishes "normal physical growth" as a quality factor for infant formula.

1. Appropriateness of a Growth Monitoring Study (GMS)

In the 1996 proposal, FDA proposed to require (§ 106.97(a)(1)) that a manufacturer conduct an adequate and well-controlled clinical study, in accordance with good clinical practice, to determine whether an infant formula supports normal physical growth when fed as the sole source of nutrition. Proposed § 106.97(a)(1)(i) would have required that the manufacturer conduct a clinical study of at least four months with study participants enrolled at no more than one month in age; that the manufacturer collect, maintain, and plot on a growth chart certain anthropometric measurements; and that these data be collected at specified times. In addition, proposed § 106.97(a)(1)(ii) included nine proposed recommendations for the protocol of the clinical study.

FDA addressed the proposed clinical study requirement in the 2003 reopening. At that time, the Agency requested comment on three specific issues related to the clinical study requirement (requirements for determining when a clinical study should be required; appropriate reference data; and the appropriate infant enrollment age). In addition, the Agency announced its intention to remove the proposed provision addressing Institutional Review Board (IRB) review and approval (proposed § 106.97(a)(1)(ii)(C)) as a result of Agency rulemaking since the 1996 proposal and its plan to remove the remaining protocol recommendations from the proposed rule and to develop a guidance document containing recommendations for the protocol for an infant formula clinical growth study (68 FR at 22342–22343).

Thereafter, in the 2006 reopening, the Agency requested comment on several recommendations of the 2004 IOM report, including the need for assessments of normal physical growth in addition to a clinical growth study, the need for body composition measurements, and the appropriate duration of and enrollment age for a clinical growth study.

This interim final rule includes a growth monitoring study requirement in § 106.96(b). This provision requires that a manufacturer of infant formula satisfy the quality factor of "normal physical growth" by conducting an adequate and well-controlled growth monitoring study to demonstrate that the formula supports normal physical growth in infants when fed as the sole source of nutrition. The interim final rule substitutes the descriptor "growth monitoring study" for "clinical study," the term used in the proposed rule, because the new term more accurately describes the nature and purpose of the study. Section106.96(b) of the interim final rule establishes requirements for the growth monitoring study, which address study duration; subject age at enrollment; data collection and maintenance; and comparison of data for study subjects and controls. In addition, parts 50 and 56 require IRB review and approval and human subject protection.

As discussed in more detail in this document, § 106.96(c) of the interim final rule provides certain exemptions from the growth monitoring study requirements under § 106.96(b).

(Comment 198) One comment recommended that a clinical growth study be required for any new infant formula, change in the infant formula, or change in the packaging of infant formula. To justify this recommendation, the comment explained that infant formula is unique in that it can be the sole source of nutrition for an infant for an extended period and during a most vulnerable time.

(Response) FDA recognizes that infant formula often serves as the sole source of nutrition for a vulnerable population during a critically important developmental period, a consideration that broadly underlies the interim final rule. To the extent that the comment suggests that a growth monitoring study be required for all formulas, including formulas that have undergone a "major change" in processing or in composition, the Agency concludes that the requirements of the interim final rule effectively achieve the outcome recommended by this comment. Specifically, § 106.96(b) of the interim final rule requires a manufacturer to conduct a growth monitoring study of each "infant formula," and § 106.96(c) of the interim final rule includes provisions for specific exemptions from that requirement where a manufacturer can establish that the formula is entitled to the exemption.

(Comment 199) One comment stated that while the future introduction of novel ingredients in infant formula (such as components of human milk not presently in infant formulas) may present new challenges to the regulatory process, safety concerns about an ingredient new to infant formula are better handled under the regulatory rubrics specifically designed for ingredient evaluation, and that FDA's Generally Recognized As Safe (GRAS) notification process provides the Agency with a context in which to raise any safety concerns, including concerns about matrix issues, processing issues, or nutrient interactions.

(Response) As discussed in detail in this document, FDA agrees in part with this comment. Ingredient safety is a basic principle of food safety, for both food generally and for infant formula specifically. As is the case with all foods, a manufacturer has an on-going responsibility to ensure the safety of each ingredient in its products and each substance produced for addition to food and to ensure that such ingredients and substances are otherwise in compliance with all applicable legal and regulatory requirements.

An ingredient newly intended for use in infant formula is appropriately evaluated under section 409 of the FD&C Act as a food additive or may be an ingredient that the manufacturer has determined to be generally recognized as safe (GRAS) under section 201(s) of the FD&C Act. For ingredients believed to be GRAS, FDA strongly encourages the formula manufacturer or the ingredient supplier to submit the self-determination of GRAS to FDA under the Agency's GRAS notification program (see 62 FR 18937, April 17, 1997) well before the submission of a new infant formula notification under section 412(c) of the FD&C Act.

Importantly, however, the review of a food additive petition under section 409 of the FD&C Act or the evaluation of a GRAS notice for an ingredient new to infant formula is separate and distinct from the provision that a formula meet the quality factor requirements under section 412(b)(1) of the FD&C Act. That is, FDA's evaluation and determination of an ingredient's safety in response to a food additive petition or FDA's response to a GRAS notice does not address the scientific issue to be addressed by the quality factors, which is whether the formula matrix and

individual nutrients in the formula support normal physical growth. In section IV.C.7. FDA explained in the discussion of the "quality factors" definition the criticality of ensuring the bioavailability of the formula's nutrients in a particular formula matrix, including the nutrients in the formula, and ensuring that an infant formula containing the new ingredient is capable of supporting normal physical growth.

Similarly, the ingredient safety review does not eliminate the responsibility of an infant formula manufacturer to make the submission required by section 412(d)(1) of the FD&C Act for each new infant formula that the manufacturer wishes to market. Under section 412 of the FD&C Act, any new formula ingredient is evaluated as part of a complete formulation, and, as noted, under section 412(d)(1)(C) of the FD&C Act, the new infant formula manufacturer must provide assurances that the formula satisfies the requirements for quality factors for specific nutrients and for the formula as a whole.

For these reasons, FDA is making no changes in response to this comment.

(Comment 200) One comment suggested that the assurances under all paragraphs of proposed § 106.97(a) be deleted from the final rule citing general legal, scientific, and policy grounds to these provisions.

(Response) As explained previously in this document, proposed § 106.97(a) has been removed from the interim final rule, and much of its content is retained in § 106.96(b) of the interim final rule. Despite this revision, FDA responds to the substance of this comment.

Infant formulas must be able to serve as the sole source of nutrition for a period of unparalleled growth and development of infants in a form that will meet all of the known nutritional needs of infants and to ensure that healthy growth and nutritional well-being will be achieved by an infant consuming the infant formula as the sole source of nutrition (61 FR 36154 at 36180). The least invasive and most practical means to ensure that the formula, as a whole, delivers nutrients in a form that is bioavailable and safe is a growth monitoring study in which anthropometric measurements of infants fed a new infant formula are assessed, and comparison of these data to a concurrent control group, in addition to comparison of both test and controls groups to a scientifically appropriate reference, is made. Anthropometric measurements are easily made, are familiar to parents and health care professionals, can be measured during outpatient study visits, and are the same measurements as those done during routine office visits.

As discussed in more detail in this document, the requirement for a growth monitoring study in § 106.96(b) of the interim final rule applies to all infant formulas that are introduced or delivered for introduction into interstate commerce. This means that a manufacturer of an infant formula for distribution in the U.S. is required to conduct a growth monitoring study under § 106.96(b) of the interim final rule, unless the manufacturer qualifies for an exemption under § 106.96(c) of the interim final rule from the growth monitoring study requirements of § 106.96(b) of the interim final rule, as explained in section VIII.C and D, respectively. A manufacturer of a "new" infant formula is required to submit such study to FDA in a 90-day submission, consistent with § 106.120 of the interim final rule and section 412(c)(1)(B) and (d)(1)(C) of the FD&C Act. As is discussed in further detail in this document, a manufacturer of an "eligible infant formula" (as defined in § 106.3 of the interim final rule) would not be required to make the submission required by § 106.120 of the interim final rule and sections 412(c)(1)(B) and (d)(1)(C) of the FD&C Act, but would be required under § 106.96(d) of the interim final rule to make and retain records demonstrating that the formula meets the quality factor of normal physical growth. The need for a growth monitoring study of an infant formula for export only is addressed in section VIII. D.

FDA recognizes that not every change in an infant formula or change in the packaging of infant formula will require a growth monitoring study. In recognition of this fact, § 106.96(c) of the interim final rule includes several exemptions from the growth monitoring study requirement, which are discussed in section VIII.D, "Exemptions From Quality Factor Requirements for Normal Physical Growth."

(Comment 201) One comment on proposed § 106.97 stated that FDA is correct to insist that new substances themselves added to formula be GRAS.

(Response) FDA believes that it is important to clarify FDA's conclusions regarding the GRAS status of substances in formula. As discussed previously in this document, all food manufacturers, including infant formula manufacturers, have a duty to ensure that the ingredients in their products satisfy the applicable statutory standard. Under section 409 of the FD&C Act, a substance added to food must be either an approved food additive or exempt from the definition of food additive because it is GRAS.

(Comment 202) One comment argued that safety issues, including the potential impact on infant growth, need to be raised and resolved, and that in order to prevent unnecessary and invasive clinical studies, animal studies should be relied upon as much as possible.

(Response) FDA disagrees with this comment for two reasons. First, the study required by § 106.96(b) of the interim final rule is a growth monitoring study and is entirely non-invasive. Indeed, the anthropometric measurements required of study participants are the same measurements that are typically taken by a health care provider at "well baby" visits. Second, FDA is not aware of an animal model that is a suitable substitute for the infants in a growth monitoring study, and the comment provided no information about such a model.

(Comment 203) One comment acknowledged that the methodology to conduct an adequate and well-controlled clinical study is scientifically ideal to answer the question of whether a new substance added to an existing formula has an effect on the bioavailability of a nutrient required for infant growth. The comment also noted that not every change in an infant formula raises questions about infant growth that cannot be answered adequately by other supporting scientific data, and provided references to sources of information that might be used for this purpose.

(Response) FDA agrees with the comment's assessment of the value of clinical study methodology to evaluate the ability of an infant formula to support the normal physical growth of infants. FDA also agrees with the comment that not every change in an infant formula would require a growth monitoring study. This issue is discussed in detail in section VIII.D.

(Comment 204) Another comment stated that routine growth studies are not designed and generally not powered to detect rarely occurring adverse events and therefore, are not comprehensive safety studies. The comment argues that new ingredients are often substances identified in human milk as having a nutritional function and that a case-by-case review of available evidence can identify when there is a need for safety endpoints in clinical studies.

(Response) Normal physical growth and protein quality are very basic benchmarks for evaluating healthy growth of infants when fed an infant formula as the sole source of nutrition. FDA agrees that growth studies are not

designed and do not have sufficient statistical power to detect rarely occurring adverse events. Importantly, however, the purpose of the growth monitoring study is to assess the ability of an infant formula, including the nutrients in the formula, to support normal physical growth. To the extent that the ingredients may present safety concerns, those issues are primarily addressed as part of the review under sections 409 and 201(s) of the FD&C Act.

2. Clinical Study Protocols

In proposed § 106.97(a)(1)(ii), FDA listed provisions that it recommended manufacturers include in a clinical study protocol. In the notice to reopen the comment period in 2003 (68 FR 22341 at 22343), FDA stated its intent to remove the clinical study protocol provisions in proposed § 106.97(a)(1)(ii) and develop a guidance document detailing the Agency's recommendations for what should be included in the protocol for a clinical study that will be submitted to FDA as "assurance" that the formula satisfies the quality factor of normal physical growth. Comments received in response to the 2003 reopening agreed with FDA's view that detailed directions for the clinical study protocols would be better addressed as guidance from the Agency. No comments were received that suggested retaining the proposed clinical study protocol provisions in the final rule. Therefore, the Agency has deleted the specific study protocol recommendations of proposed § 106.97(a)(1)(ii).

However, as discussed in section VIII. C., §§ 106.96 and 106.121 of the interim final rule incorporate some of the proposed study protocol recommendations as requirements in the interim final rule. To the extent that proposed recommendations have become requirements, FDA will address the comments received on those specific recommendations. Otherwise, the Agency is not individually addressing the comments submitted on those recommendations not incorporated into the interim final rule. FDA will consider developing guidance in the future on the protocol for a growth monitoring study of infant formula and will consider relevant comments during the development of such guidance.

As stated previously in this interim final rule, FDA has not included all of the clinical study protocol recommendations that were included in the 1996 proposal. The Agency has concluded, however, that certain basic elements of study design, data collection, and evaluation are necessary to ensure that a growth monitoring study provides the quality and type of data needed to evaluate whether an infant formula supports normal physical growth when fed as the sole source of nutrition. Therefore, those elements have been codified in §§ 106.96(b) and 106.121 of the interim final rule. In the responses to the comments that follow, FDA explains the reasons for including these elements.

3. Design of a Growth Monitoring Study

a. *Appropriate study design.* Several comments addressed the design of growth monitoring studies of infant formulas.

(Comment 205) One comment stated that the requirement in proposed § 106.97(a)(1) that the study be "well-controlled" was too vague to be meaningful and suggested that acceptable controls should be specified.

(Response) For several reasons, FDA disagrees with this comment and declines to specify acceptable controls for infant formula growth monitoring studies. First, the concept of "well-controlled" is generally well understood in the scientific community. The primary purpose of conducting a well-controlled study is to distinguish the effect of the treatment (here, feeding of the infant formula being evaluated) from other influences, such as chance occurrences, normal growth, or biased observation. A well-controlled study methodically examines sameness and differences in outcomes across cohorts and permits an organized comparison and the delineation of sameness and difference.

Further, it would be unnecessarily restrictive to identify in a regulation the specific type or types of controls that, if used in a growth monitoring study, would make the study "well-controlled." The appropriateness of a particular control group or of other controls is determined in part by the nature of the study and of the group being studied. Accordingly, it is not possible for FDA to specify *a priori* the controls relevant and appropriate to a particular growth monitoring study. Thus, FDA is not revising this provision in the interim final rule to elaborate on the controls needed to make an infant formula growth monitoring study "well-controlled."

To the extent that the interim final rule addresses the specific requirements of a growth monitoring study, FDA has clarified, by adding § 106.96(b)(4) and (b)(5) to the interim final rule, that the protocol of a well-controlled growth monitoring study would require information on infant formula intake for both the test and control groups. A study that lacks formula intake data would be difficult to interpret and could lead to erroneous conclusions regarding the formulas being fed. Clearly, the relationship between formula intake and growth is basic to the evaluation of an infant formula's capacity to support normal physical growth. Therefore, any study of infants in which normal physical growth is being assessed would include the collection of formula intake data as part of the design of the study. These data are needed to provide fair and meaningful interpretation of the study results and to demonstrate whether the new formula is able to support normal physical growth. To clarify the specific controls expected in a study designed to evaluate whether an infant formula supports normal physical growth when fed as the sole source of nutrition, FDA is adding § 106.96(b)(2) to the interim final rule to require the growth study to include collection and maintenance of data on infant formula intake and § 106.96(b)(5) to require comparison of the data on formula intake of the test group(s) and control group(s), with each other and with a scientifically appropriate reference to determine whether both groups had consumed age appropriate volumes.

(Comment 206) Another comment stated that the design of the study should address the specific objectives of the study.

(Response) FDA agrees with this comment. One characteristic of an adequate and well-controlled study is that the protocol for the study includes a clear statement of the study objective(s). Likewise, a report of study results should also contain a clear statement of the objective of the investigation. *See,* e.g., 21 CFR 314.126(b)(1) and 514.117(b)(1).

(Comment 207) One comment stated that a randomized clinical study, with or without reference to an outside standard, is the best method to assess whether infants receiving different feeding regimens differ in terms of a primary outcome parameter. The comment also stated that this research methodology is recognized as the most definitive method of determining whether an intervention has the postulated effect.

(Response) FDA agrees that a randomized study design is generally regarded as the strongest experimental design to determine whether an intervention (i.e., feeding a new formulation of an infant formula) has the postulated effect because this study design requires a concurrent control group. For this reason, the interim final rule requires that the growth monitoring study of an infant formula be an

adequate and well-controlled study, which would include randomizing study participants into the treated and control groups.

Indeed, the purpose of a growth monitoring study is to evaluate whether an infant formula supports normal physical growth by comparing the growth of infants consuming the test formula with the growth of infants consuming a baseline formula. Although weight is the most sensitive indicator of infant growth, no single anthropometric measurement provides all the information needed to assess growth. Measures of length and head circumference provide additional information on whether the formula supports normal physical growth. Plotting these measures on growth charts for each infant in the test and control groups provides information about how the infants in both groups are growing compared to a reference population of infants. Plotting weight and length on the weight for length charts is an additional safety check that the infant is growing proportionally (not too thin or too heavy for the measured length) relative to the norms represented by the charts.

FDA received several comments on the proposal to require concurrent control groups.

(Comment 208) One comment disagreed with the Agency on the value of a concurrent control group in studies conducted in accordance with proposed § 106.97(a)(1). The comment asserted that historical control data based on normal infants are available from Fomon and Nelson (Ref. 68) and Guo et al. (Ref. 69) and that these data are generally more appropriate than concurrent controls because the data are based on a large number of normal infants studied under well-defined conditions.

(Response) FDA disagrees in part with this comment. The optimal comparator for infants consuming a new formulation of an infant formula is a concurrent control group of infants fed a base formula. For this reason, § 106.96(b)(4) and (b)(5) of the interim final rule require that a growth monitoring study of an infant formula use a concurrent control group.

FDA acknowledged in the 1996 proposal that historical controls have been used by some investigators to evaluate infant growth while being fed a new formulation of a formula. Importantly, however, the Agency noted that historical controls have inherent limitations, and the differences and similarities in growth between the study infants and the population reference standard cannot be meaningfully compared (61 FR 36154 at 36183). For example, difficulties in interpretation may arise when the sample of infants receiving the test formula differs significantly from the population in the historical controls; when the variability in measures of growth in test subjects is large; when attrition rates differ greatly between the population in the historical controls and the infants on test; and when events occurring in the study cannot be explained in the absence of concurrent controls.

FDA recognizes that historical control data may be useful in certain limited situations in which a manufacturer has access to extensive reference data, such as a database on many similarly conducted studies in which infants were selected on the basis of nearly identical criteria, and the results are available for all important measurements, including formula intake and attrition rates. FDA notes that the manufacturer is responsible for demonstrating that a new formulation of an infant formula satisfies the quality factor of normal physical growth. Thus, when designing a study protocol, the manufacturer should carefully consider whether historical control data permit a meaningful comparison to the infants consuming the new formulation.

Because the use of historical control data may be appropriate in certain narrow circumstances, the interim final rule provides manufacturers with an opportunity to justify reliance on such data. Specifically, a manufacturer may request an exemption under § 106.96(c)(2)(i) of the interim final rule to conduct a growth monitoring study using an alternative study method or design, provided that the manufacturer provides assurances that demonstrate that the alternative study design is based on sound scientific principles. In such a situation, FDA expects that detailed study results from the historical control data would be available to FDA for review.

(Comment 209) One comment stated that because growth may or may not be the crucial outcome measured in future formula studies and "optimal" growth and development have yet to be defined, a concurrent control group is the optimal comparator.

(Response) FDA agrees with this comment. As noted, in the 1996 proposal, the Agency acknowledged that although historical controls have been used in some infant formula investigations, these historical data have inherent limitations. Accordingly, § 106.96(b)(4) and (b)(5) of the interim final rule require that a growth monitoring study of an infant formula use a concurrent control group. Importantly, if a manufacturer wishes to utilize historical control data in a growth monitoring study, the manufacturer may request an exemption under § 106.96(c)(2)(i) of the interim final rule.

(Comment 210) One comment recommended a concurrent breastfeeding control group, while another comment opined that the universally agreed reference population that defines healthy growth as infants breastfed by well-nourished mothers cannot be included in a randomized trial.

(Response) A growth monitoring study need not include a concurrent control group of breast-fed infants because comparing the growth of infants consuming the new formulation to that of a concurrent control group consuming the control formula and to the appropriate reference data is sufficient to assess whether the new formula supports normal physical growth. Also, infants cannot be randomly assigned to be formula-fed or breastfed so there are scientific limitations on the use of a concurrent breast-fed control group. In addition, there may be significant non-nutritional confounding factors with using breastfed infants as a control group, such as the health and nutrition of the mothers who choose to breastfeed. The Agency would not object, however, if breastfed infants from the same population as the infants consuming the infant formula under evaluation were included as a concurrent cohort group. In such circumstances, the growth of breast-fed infants could also be compared to the group of infants consuming formula as a model or reference for growth.

(Comment 211) Another comment indicated that it may be necessary to have a concurrent control from the same population if infants believed to have different growth characteristics (e.g., infants from different ethnic groups) are used as the study population.

(Response) FDA agrees in part with this comment. The Agency acknowledges that the optimal comparator for a particular growth monitoring study is a concurrent control group composed of infants that mirror the study infants as closely as possible, including ethnic or racial background. Importantly, however, the Agency is aware that the pool of infants for study subjects and controls is limited and thus, FDA is concerned that to require precise ethnic or racial comparability between study and control group members could inhibit the ability to recruit subjects and fulfill the growth monitoring study requirement.

Accordingly, FDA encourages manufacturers to consider factors such as ethnic or racial background in developing test and control groups, but the Agency declines to specify that such comparability is a necessary characteristic of an adequate and well-controlled investigation.

(Comment 212) One comment stated that infant formulas should be clinically tested in randomized trials and conducted in at least two centers.

(Response) FDA agrees with this comment to the extent that it asserts that a new formulation of an infant formula should be evaluated in a randomized, well-controlled growth monitoring study to demonstrate satisfaction of the quality factor of normal physical growth. Like all study designs, studies conducted at multiple centers have advantages and disadvantages. For example, the use of multiple centers may be advantageous because it may make it easier to recruit sufficient numbers of infants as study subjects. However, the failure to follow the study protocol carefully at all centers may jeopardize the utility of the combined data and thus, is a potential disadvantage to a multi-center study. Such factors as an appropriate study design (including suitable control groups and treatments, blinding of all caregivers and study evaluators, and selection of appropriate outcome measures), strict adherence to protocol requirements, adequately trained and experienced study personnel, and appropriate management and analysis of study data are critical determinants of the quality and thus, ultimate value of a growth monitoring study. Therefore, FDA declines to require that a growth monitoring study be conducted in at least two centers.

(Comment 213) One comment stated that clinical trials of infant formula should have a low attrition rate of subjects in each feeding group (preferably below 10 percent) as well as effective blinding of the study subjects' caregivers and study evaluators to the feeding group, whenever feasible.

(Response) FDA acknowledges that minimizing attrition in a growth monitoring study is highly desirable because a high dropout rate may introduce bias or otherwise compromise interpretation of the study data. However, the comment did not provide a basis for the Agency to require an attrition rate below 10 percent in an infant formula growth monitoring study, and the Agency declines to do so. It is often difficult to ensure a low attrition rate (e.g., below 10 percent) in investigations, especially with infant subjects. Importantly, FDA expects that study investigators and the manufacturer/sponsor will thoroughly investigate and explain all dropouts. FDA intends to monitor closely attrition rates in infant formulas growth monitoring studies and will consider that higher than anticipated attrition rates may signal cause for concern about the use of a particular formulation. Thus, FDA is not making changes to the rule in response to this comment.

(Comment 214) One comment asserted that as the changes in formulas become more subtle, such as through the addition of long chain polyunsaturated fatty acids (LCPUFAs), outcome measures must include other relevant effects such as those on visual acuity and intelligence, which may only become measurable months to years after formula consumption. For this reason, the comment observed that this will require manufacturers to conduct post-marketing surveillance as a part of every formula study.

(Response) This comment is not relevant to the issues in this rulemaking. The interim final rule requires a single type of study in infants: a growth monitoring study. The purpose of a growth monitoring study is very narrow and specific: to evaluate the bioavailability of the infant formula, including its nutrients, that are required to be in infant formula by section 412 of the FD&C Act to ensure that, during the period that such formula serves as the sole source of nutrition for infants, such infants experience normal physical growth. Contrary to suggestion of the comment, a growth monitoring study is not designed to evaluate whether there is a benefit of added ingredients such as LCPUFAs like arachidonic acid (ARA) and docosahexanoic acid (DHA). Accordingly, FDA is not responding to the comment's recommendation for post-marketing surveillance for such purpose.

b. *Age of enrollment for a growth monitoring study.*

In 1996, FDA proposed in § 106.97(a)(1)(i)(A) that manufacturers shall "conduct a clinical study that is no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study" (61 FR 36154 at 36215). In 2002, the Infant Formula Subcommittee of the FDA Food Advisory Committee recommended that infants be enrolled into clinical growth studies by 14 days of age (*http://www.fda.gov/ohrms/dockets/ac/cfsan02.htm0*), and in 2004, the IOM recommended a duration of 6 months (180 days) for growth studies of infants (Ref. 4, p. 10). In the 2003 reopening (68 FR 22343) and in the 2006 reopening (71 FR 43392 at 43397–43398), the Agency expressly requested comment on the appropriate age for enrollment of infants into growth monitoring studies.

FDA received several comments regarding the age of subject enrollment for growth monitoring studies.

(Comment 215) One comment stated that there is a rationale for including infants not older than 14 days because this early period is the time of greatest nutrient requirement and greatest sensitivity to nutrient adequacy. Another comment suggested enrollment by 14 days of age in order to ensure a 4 month observation period before other foods are introduced into the infant's diet.

(Response) FDA agrees with the recommendations of these two comments and thus, § 106.96(b)(1) of the interim final rule requires that subjects in a growth monitoring study be no more than 2 weeks of age at the time of enrollment. FDA included this age requirement in the interim final rule for both data quality and practical reasons.

There are three data quality reasons for establishing 14 days as the maximum age of enrollment in a growth monitoring study. First, early infancy is the period of greatest nutritional risk and the period during which infants experience the most rapid growth. Thus, testing a new formulation of a formula during this time period means that the infant formula will be evaluated under the most demanding conditions of use. Second, the earliest days of an infant's life are the most sensitive in that this phase includes the most dramatic (and thus most readily measurable) growth. Thus, a study including this period would be most likely to detect deficiencies in normal physical growth. Finally, by enrolling study participants at age 2 weeks or less, it will be possible to conduct a growth monitoring study of an appropriate length before an infant begins to consume a mixed diet. Health care professionals currently recommend adding other foods (such as cereal, strained vegetables, pureed fruits) to an infant's diet between the ages of 4 to 6 months. (*http://www.fns.usda.gov/tn/Resources/feddinginfants-ch2.pdf*). When an infant is consuming such a mixed diet, study data are likely to be difficult to interpret because dietary intake is less controlled.

There is also a practical reason for establishing 14 days as the maximum enrollment age for growth monitoring study participants. Most health care professionals recommend that a newborn have his/her first well-child visit at 3 to 5 days of age (Ref. 70) and another during the second week after birth. Thus, the period of study enrollment coincides with infant age

range for an early well-child visit which will likely enhance recruitment of study participants and thereby, support the quality of the growth monitoring studies conducted on new formulations of infant formulas.

(Comment 216) One comment stated that for routine growth studies, infants would ideally be enrolled by approximately 14 days of age. However, the comment further stated that there is no biological reason why any enrollment age short of one month should disqualify an infant from such a study and noted that in 1993, the European Commission Scientific Committee on Food recommended subjects be entered into a study within the first month of life.

(Response) FDA agrees with this comment to the extent that it suggests that subjects be enrolled in growth monitoring studies at no more than 14 days of age. Importantly, the comment did not provide data to support the assertion that there is no biological reason that enrollment up to one month of age should disqualify an infant from a growth monitoring study. In fact, as discussed previously in this document, early infancy is the period of greatest nutritional risk and also most rapid growth; both of these biological factors have the potential to enhance the quality of the data generated in a growth study.

(Comment 217) Two comments agreed with FDA's 1996 proposal to require study subjects to be enrolled during the first month of life.

(Response) For the reasons outlined previously in this document, FDA has revised the required enrollment age for the growth monitoring study to 14 days or less, a decision based on the fact that 14 days is the optimal age for enrollment because this age will capture the period of subjects' greatest nutritional demand and greatest growth.

(Comment 218) One comment stated that a study to assess the nutritional adequacy of a formula to be fed during the first year of life by measuring weight gain (Ref. 67) should be initiated within the first month of life. However, if the formula is for a different age range, the design of the study should reflect this difference.

(Response) FDA does not agree with this comment. As explained previously in this document, in § 106.96(b)(1) of the interim final rule, the Agency is establishing 2 weeks as the maximum age at time of enrollment for subjects in a growth monitoring study because this age will capture the most sensitive period of infant growth and the period of greatest nutritional need.

In addition, the Agency does not agree that the interim final rule should establish a different enrollment age for a study of a formula intended for a "different age range." First, even if a product is marketed for use in older infants, e.g. those older than 6 months of age, the product is an "infant formula" within the meaning of section 201(z) of the FD&C Act and 21 CFR 105.3(e). As such, the formula must satisfy the nutrient requirements of section 412(i) of the FD&C Act and § 107.100 and the quality factor requirements established in § 106.96 of the interim final rule under section 412(b)(1) of the FD&C Act. As noted, the appropriate age of enrollment for a study of an "infant formula" is 14 days or less. Second, even if a particular product is marketed for "older" infants, there is a possibility that it will be fed to neonates. For this reason, it is essential that the formula be nutritionally adequate for these younger infants. Testing the formula in very young infants will maximize the certainty that such formula will be nutritionally sufficient for all infants, including neonates. Third, as noted previously in this document, data from studies conducted in older babies may be difficult to interpret because such infants are likely to be consuming a mixed diet. Finally, if a manufacturer believes that the growth monitoring study of a particular formula should have an enrollment age other than that established in § 106.96(b)(1) of the interim final rule, the manufacturer may request an exemption under § 106.96(c)(2)(i) of the interim final rule.

(Comment 219) One comment asserted that the final requirement should be more stringent than the proposed, and suggested that infants should be enrolled in clinical studies before the end of the first postnatal week. Another comment made a similar suggestion, stating that the growth monitoring study should enroll infants at 8 days of age.

(Response) FDA acknowledges that early infancy is the period of greatest nutritional risk and the age at which the most rapid growth occurs, both of which make this time period the most demanding conditions for use of a formula. Although initiating a growth monitoring study by the end of the first postnatal week or at 8 days of age would capture a greater portion of this period, FDA is concerned that this limit on enrollment age could unduly restrict recruitment and participation in the required growth monitoring studies. Establishing 14 days as the maximum age of enrollment strikes a reasonable balance between acquiring high quality data and providing flexibility to foster recruitment of study subjects.

c. *Duration of a growth monitoring study.* As noted, proposed § 106.97(a)(1)(i)(A) would have required that a manufacturer "conduct a clinical study that is no less than 4 months in duration" (61 FR 36154 at 36215). In its 2004 report, the IOM recommended that a growth study should cover at least the period when infant formula serves as the sole source of nutrients in the infant diet (Ref. 4, p. 108). Accordingly, at that time, the Committee recommended a study of 6 months (180 days) because such duration would mirror the recommended length of time an infant should consume human milk exclusively. However, because current infant feeding recommendations are to begin solid foods between the ages of 4 and 6 months, the IOM acknowledged that it would be difficult, as a practical matter, to convince parents of study subjects to postpone such introduction until age 6 months. In the 2003 reopening (68 FR 22343) and in the 2006 reopening (71 FR 43392 at 43397–43398), the Agency expressly requested comment on the appropriate duration of a growth monitoring study.

In addition to the IOM recommendation, FDA received several comments regarding the appropriate duration of growth monitoring studies.

(Comment 220) One comment noted that the IOM report recommended that a growth monitoring study of an infant formula containing a new ingredient be at least 6 months (180 days) in duration, and that this recommendation was based on the use of formula as a substitute for human breast milk and the current advice of the AAP that infants be exclusively breastfed for at least 4 and, preferably, 6 months. The comment expressed concern that the data from a 6-month study would be confounded by the introduction and inclusion of complementary foods in the diets of study subjects.

(Response) FDA agrees with this comment for several reasons. First, current recommendations are to begin solid food between the ages of 4 and 6 months. The comment noted, the IOM report acknowledged, and FDA agrees that feeding complementary foods to study subjects could confound the study results of a 6-month study. The IOM report also acknowledged that it would be difficult, as a practical matter, to convince parents of study subjects to postpone such introduction until age 6 months. Second, the IOM report noted that it would be unlikely that adverse effects would appear only between 4 and 6 months if none appeared between birth and 4 months, suggesting that no

significant information on adverse effects would be lost from a shorter study. FDA agrees with these observations and concludes that a study of 4 months duration would provide the data and information necessary for a manufacturer to evaluate the ability of an infant formula to support normal physical growth. Importantly, however, FDA would not discourage an infant formula manufacturer from conducting a growth monitoring study of 6 months' duration if the manufacturer is able to address the potentially confounding effect of complementary food consumption during the study period.

(Comment 221) One comment recommended that the growth studies of infants be conducted from 8 to 112 days of age (a time interval of 15 weeks). The comment noted that a study period of 8 to 112 days of age would permit young infants to participate, and noted that such infants may be the most sensitive subjects for demonstrating inadequacies of infant formulas. The comment also observed that the period of 8 to 112 days of age has been used extensively in clinical studies of growth of formula-fed infants and that the data from these studies have been used to generate historical control data on gains in weight and length during infancy (Refs. 68 and 69).

(Response) Although enrollment at age 8 days may provide an additional week to evaluate growth during the most sensitive growth period, FDA finds that some flexibility is needed for the enrollment timeframe. Section 106.96(b)(1) of the interim final rule permits infants to be enrolled in the growth monitoring study up to age 14 days. FDA has explained its reasons for selecting 14 days as the maximum enrollment age in responding to the comments in the immediately previous section of this preamble.

The Agency agrees with this comment to the extent that it recommends a growth monitoring study of at least 15-weeks duration. As the comment noted, the 15-week duration has been used extensively for infant growth studies (Ref. 68), which provides a sound basis for choosing this period for the growth monitoring studies required by this interim final rule. Also, 15 weeks is a reasonable study duration because this period maximizes the time between enrollment (2 weeks of age) and the age at which many infants begin to consume a mixed diet (17 weeks or 4 months). As explained previously in this document, the consumption of a mixed diet by study subjects may complicate interpretation of the study results regarding the nutritional sufficiency of the test formula because, with a mixed diet, the formula is no longer the sole source of nutrition for the infant. Accordingly, FDA has revised the interim final rule to require a growth monitoring study to be at least 15 weeks in duration.

(Comment 222) One comment recommended that, as an alternative, a growth study be at least four months in duration, enrolling infants at no more than one month of age. The comment noted that a 4-month study period permits a slightly longer period of observation (as compared to a 15-week study) and would provide greater ease of subject recruitment.

(Response) FDA disagrees with this comment and notes that this alternative suggestion is what the Agency proposed in 1996 in proposed § 106.97(a)(1)(i)(A). FDA has concluded that the appropriate duration for a growth monitoring study is 15 weeks and that study subjects should be no more than 14 days old at the time of enrollment. The Agency's reasons for these determinations are explained in its response to the foregoing comments.

(Comment 223) One comment stated that growth studies are usually conducted for 14 weeks (98 days), with subjects participating from approximately age 14 days until age 112 days (i.e., from 2 to 16 weeks of age). The comment also noted that in 1993, the European Commission Scientific Committee on Food proposed a study period of at least 3 months to evaluate the nutritional adequacy of infant formula.

(Response) FDA disagrees with this comment to the extent that it recommends a study of 14 weeks. Although the comment asserted that growth studies are "usually" of 14 weeks duration, the comment provided no data or other rationale to support the validity or sufficiency of this length of a growth monitoring study. FDA has determined that a 15 week study requirement is reasonable for the reasons provided in previous comment responses.

(Comment 224) One comment asserted that selection of 16 weeks or 3 months, or 4 months as originally proposed by FDA, are based on convenience and current well-baby visit schedules and not based on the scientific assessments of sensitivity, validity, or the relationship of growth over this period to health.

(Response) FDA disagrees with this comment. As explained in the response to Comment 221 the 15-week study duration maximizes the time during which study subjects are likely consuming the formula as the sole source of nutrition. Once study subjects begin to consume a mixed diet, the resulting data are more difficult to interpret because it is not possible to distinguish between the nutritional effects of the formula and the nutritional effects of the remainder of a subject's diet, thereby hampering the accurate assessment of the nutritional sufficiency of the formula.

(Comment 225) One comment recommended that growth studies of infant formulas would ordinarily require testing through 8 to 12 months of age in order to evaluate the formula throughout the period that it serves as the only or main source of calories. Another comment stated that because infant formula is given to babies from birth until 12 months of age, 12 months is the appropriate duration of time for a study.

(Response) FDA disagrees with these comments. In order to perform an accurate assessment of the nutritional adequacy of an infant formula, there must be no competing or supplemental sources of nutrition consumed by the study subjects. That is, if the study subjects are consuming other foods, any results showing normal physical growth may be attributable to the other foods and not to the infant formula. For this reason, proposed § 106.97(a)(1) stated that the growth monitoring study must determine whether the formula supports normal physical growth "when the formula is fed as the sole source of nutrition." As explained previously in this document, health care professionals generally suggest that infants begin to consume a mixed diet sometime after 4 months of age. Thus, it would be difficult if not impossible to conduct a growth study with subjects 8 to 12 months of age without including infants on a mixed diet and thereby, compromising the study results. Also, physical growth rates slow after early infancy, thereby resulting in a less sensitive measure to detect differences in the ability of an infant formula to support normal physical growth.

(Comment 226) Another comment stated that studies should extend for years rather than months to detect the subtle effects of formula feedings.

(Response) FDA has considered whether extending the duration of growth monitoring studies to 12 months or longer has merit and has concluded that it does not. The rate of physical growth in infants slows after early infancy, thereby resulting in a less sensitive measure to detect differences in the capability of a new formulation of an infant formula to support normal physical growth. Also, consumption of foods other than infant formula (typically started at about 4 to 6 months

of age) has the potential to confound the growth monitoring study results from beyond the period when infant formula is consumed as the sole source of nutrition.

Based on the foregoing, FDA is redesignating proposed § 106.97(a)(1)(i)(A) as § 106.96(b)(1) in the interim final rule and revising the provision to require a growth monitoring study that "[i]s no less than 15 weeks in duration, enrolling infants no more than 2 weeks old at the time of entry into the study;".

d. Review by institutional review board and protection of human subjects. In the 1996 proposal, FDA recommended in proposed § 106.97(a)(1)(ii)(C) that the study conducted under proposed § 106.97(b) be reviewed by an IRB in accordance with 21 CFR part 56 and that the manufacturer establish procedures to obtain informed consent from the parent or legal representative of each study participant. Thereafter, in the 2003 reopening (68 FR 22341 at 22343), FDA proposed to delete the provisions relating to IRB review and informed consent due to an independent FDA rulemaking (66 FR 20589, April 24, 2001), one effect of which was to make an infant formula growth monitoring study subject to the requirements of parts 50 and 56. Specifically, under parts 50 and 56, data and information about a clinical study of an infant formula, when submitted as part of an infant formula notification under section 412(c) of the FD&C Act, constitute an "application for research or marketing permit" and thus, are subject to the informed consent and IRB requirements related to such permits in parts 50 and 56. Accordingly, as proposed in the 2003 reopening, FDA is not including provisions relating to IRB approval and human subject protection in the interim final rule because such provisions are unnecessary as the requirements are codified in parts 50 and 56.

4. Collection and Evaluation of Anthropometric Data

In 1996, FDA proposed to require that a growth monitoring study include the collection of anthropometric measures of physical growth, including body weight, recumbent length, head circumference, and average daily weight increment. Under the 1996 proposal, the anthropometric measurements would have been required at the beginning of the study, at 2 weeks, at 4 weeks, and at least monthly thereafter. Subsequently, in the 2003 reopening, FDA requested comment on whether certain Iowa data (which were discussed at the November 2002 meeting of FDA FAC's Infant Formula Subcommittee) should serve as the comparison for the anthropometric data collected during a growth monitoring study (68 FR 22341 at 22342–22343).

In addition, in the 2006 reopening, in response to a recommendation in the IOM report, FDA requested comment on whether the Agency should require body composition measurement in a growth monitoring study conducted under the interim final rule. At that time, FDA stated its tentative conclusion that measures of body weight, recumbent length, head circumference, and data to calculate average daily weight increment would be adequate to assess the quality factor of normal physical growth (71 FR 43392 at 43397).

In 1996, FDA also proposed that the anthropometric data be plotted against 1977 reference curves ("growth charts") from the National Center for Health Statistics (NCHS). The 1977 NCHS growth charts were substantially revised in 2000 and were referred to as the 2000 CDC growth charts (Ref. 72).

In 2006, WHO released a new international growth standard for children ages birth to 59 months that reflects normal physical growth for all infants and children. For infants and children less than 24 months of age, the WHO standard includes charts based on measurements of weight for age, length for age, weight for length, and head circumference (Ref. 11). Thus, after 2006, two sets of growth charts, the 2000 CDC growth charts and the 2006 WHO growth standards, were available for assessing early childhood growth. On September 10, 2010, CDC formally announced its recommendation that the WHO growth standards be used to plot the growth of infants and children from birth to 24 months of age (published in November 2009).

The WHO growth standards are based on a high quality comprehensive, longitudinal, world-wide study conducted in healthy women and their breast-fed infants and included subjects from six countries, including the United States, drawn from different ethnic and racial populations. Anthropometric measurements of the infants were obtained at birth and five additional times between birth and 8 weeks of age. CDC considered the WHO study design and results, and conducted expert consultations with National Institutes of Health and the AAP, and determined that the longitudinal measurements of the WHO study provide the best available information on which to base growth curves, rather than the mathematical modeling used to develop the 2000 CDC growth charts. CDC described these WHO growth standards as providing the standard for how infants and children (birth to 24 months) should grow regardless of the type of feeding.

The interim final rule incorporates the new CDC recommendation. Specifically, § 106.96(b)(4) of the interim final rule requires that the anthropometric measurements obtained in a growth monitoring study be plotted on the 2009 growth charts recommended by the CDC based on the WHO Child Growth Standards (2009 CDC growth charts), as incorporated by reference in § 106.160 of the interim final rule. This is a reasonable outcome for the interim final rule for two reasons. First, it is appropriate for FDA to defer to CDC's recommendation on this issue as CDC is the relevant authoritative public health Agency. Second, the basis for the CDC's recommendation is sound scientifically and is one with which FDA agrees. In particular, the WHO Child Growth Standards, on which the 2009 CDC growth charts are based, are derived from a longitudinal study of a number of diverse populations with relatively frequent growth measurements. As such, the 2009 CDC growth charts describe growth of healthy children under optimal conditions whereas the 2000 CDC charts describe how certain children grew in a particular place and at a particular time (Ref. 11).

a. *Measuring body composition.*

(Comment 227) One comment recognized that there may be occasions in which an assessment of body composition might be appropriate but did not further elaborate what those occasions might be.

(Response) FDA notes that this comment did not explain when or why body composition measurements are needed to assess normal physical growth. Thus, FDA is not revising the rule in response to this comment.

(Comment 228) One comment disputed the IOM's recommendation to measure body composition as part of the assessment of normal physical growth. The comment asserted that body composition is not easily measured in newborns and young infants and there are few references or standards. The comment also claimed that there is potential for a great deal of error with such measurements and that some methods of measurement would require infants to be exposed to radiation, which would be unacceptable. Two other comments stated that sufficient reference data for infant body composition do not exist.

(Response) FDA agrees with these comments. The Agency has considered

whether body composition measurements should be required as a means to assess physical growth and has concluded that such measurements should not be required because these measurements are not easily made in newborns and young infants. In addition, as the comment noted, references and standards are lacking, which means that even if the measurements could be readily made, it would be difficult to assess their significance. Also, as suggested in the comment, some risk is associated with any radiation exposure (Ref. 71). Without an established need for body composition data and a sound means to assess their significance, FDA concludes, that, at this time, any risk from the use of radiation in healthy newborns and young infants would not be justified.

(Comment 229) One comment asserted that facilities and equipment for body composition measurement are not standardized and are not readily available, which would make it more difficult to conduct growth monitoring studies, and including such a requirement would add to the cost of such studies.

(Response) The comment did not include any data to support its assertions about facilities and equipment availability to measure infant body composition and FDA is not independently aware of such availability information. The Agency has concluded, in view of the challenge of making these measurements, the problems with measurement accuracy, and the lack of suitable reference standards, not to require body composition to be measured in growth monitoring studies conducted under this interim final rule. Therefore, the interim final rule will not require the growth monitoring study to include body composition measurements.

b. *Collection and maintenance of appropriate anthropometric data.*

Several comments addressed the specific anthropometric measurements identified in proposed § 106.97(a)(1)(i)(B) to assess physical growth, including a number of comments supporting the Agency's proposed use of body weight, recumbent length, and head circumference for such purpose.

(Comment 230) One comment requested that recumbent length measurements be excluded from the study requirements because such measurements in young infants may involve considerable error. The comment recommended that recumbent length continue to be measured as part of the standard growth protocol, allowing for calculation of BMI and some body composition measures as needed, but that these data not be routinely reported to the Agency.

(Response) FDA disagrees with this comment. As noted in the 1996 proposal (61 FR 36154 at 36183), "[g]ains in weight and length of young infants reflect the long-term, integrative physiological processes that can only be achieved if the infant's nutritional needs are met." Accordingly, recumbent length, along with head circumference, provides a valuable context for interpreting weight change data. Changes in length and head circumference data provide especially valuable information for interpretation of the weight change data in those situations in which weight change with a test formula is significantly different than the weight change attained with the control formula. Also, careful training of the persons who make the recumbent length measurements will help to minimize errors. Therefore, FDA is not removing the requirement to make recumbent length measurements in response to this comment.

(Comment 231) Several comments recommended the exclusion of head circumference measurements, claiming that head circumference is not responsive to small changes in nutritional status citing the conclusion of the 1988 CON/AAP consultation (Ref. 67).

(Response) FDA disagrees with this comment. As noted, recumbent length and head circumference provide a valuable context for interpreting weight change data. The conclusion of the CON/AAP consultation (Ref. 67), cited as support by the comment, applies to a situation in which no significant difference is observed in weight change. Head circumference measurement may not be as responsive as body weight as an indicator of nutritional status. However, because such measurements can be routinely made, are not invasive, require no specialized equipment, and are not expensive, the value of head circumference measurements outweighs any risk or cost of collecting these data.

(Comment 232) One comment asserted that the most sensitive method of evaluating infant growth is a comparison of increments in recumbent length and body weight over time (e.g., millimeters/day or grams/day) rather than comparison of absolute size (e.g., length (centimeters) or absolute weight (grams)) at a given age. The comment identified what it characterized as suitable reference data (Refs. 68 and 69) for evaluation of incremental changes in weight and length.

(Response) FDA agrees that body weight and rates of change in body weight are useful measures of changes in body mass in the newborn and the young infant, and that recumbent length and head circumference measurements provide information for interpreting these weight change data. In the 1996 proposal, the Agency proposed to require in § 106.97(a)(1)(i)(B) that data on "average daily weight increment" be collected and maintained as part of the growth monitoring study. At that time, however, the Agency did not propose to require the collection and maintenance of incremental recumbent length data. FDA agrees with this comment that incremental gains for both body weight and recumbent length provide sensitive comparisons of anthropometric growth measurements in young infants. For this reason, the Agency expects that these calculated values will be part of a manufacturer's analysis of its growth monitoring study on a new formulation of an infant formula. Accordingly, § 106.96(b)(2) of the interim final rule requires that a growth monitoring study include the collection and maintenance of data on anthropometric measures of physical growth, including body weight, recumbent length, head circumference, average daily weight increment, and average daily recumbent length increment.

c. *Schedule for and frequency of anthropometric measurements.*

Section 106.97(a)(1)(i)(C) of the 1996 proposed rule would have required that the anthropometric measurements in the growth monitoring study be collected at the beginning of the study, at 2 weeks, at 4 weeks, at least monthly thereafter, and at the study's conclusion. The Agency received a number of comments on this proposed requirement.

(Comment 233) One comment requested that proposed § 106.97(a)(1)(i)(C) be deleted and recommended that the frequency of body weight measurements be addressed in guidance and not in the regulation.

(Response) FDA disagrees with this comment. It is important to specify the frequency and the schedule for anthropometric measurements in the growth monitoring study. This will ensure that the study data will be of sufficient quality to evaluate whether the new formulation of the infant formula supports normal physical growth. As noted earlier, Agency guidance is not binding and thus, even if the frequency of the measurements was specified in guidance, a manufacturer would be free to establish a schedule and frequency of anthropometric measurements that

deviated from the Agency's best thinking. As a result, the study data may not provide an adequate basis for evaluating the formula's ability to support normal physical growth.

(Comment 234) One comment stated that the proposed frequency of measurement is unnecessarily burdensome to parents facilitating their infants' participation in the growth studies because several of these times do not coincide with a regularly scheduled well-baby visit. The comment further asserted that clinical studies of new formulas are often delayed because it is difficult to recruit sufficient numbers of participants. The comment included a study design schematic that illustrated the recommended frequency for anthropometric data collection as follows:

STUDY DESIGN SCHEMATIC

Scheme of data collection						
	Enrollment visit [1]	14 days of age [2]	28 days of age [2]	56 days of age [2]	84 days of age [2]	112 days of age [2]
Enrollment/Randomization	X					
Demographic Data	X					
Weight, Length	X	X	X	X	X	X
Interval History	.....	X	X	X	X	X
Adverse Events	X	X	X	X	X	X

[1] Date of Birth is Day Zero of life (enrollment 0–14 days of age); enrollment may be on day 14 of age visit.
[2] Visit window ± 3 days.

(Response) In the 1996 proposal, FDA addressed the timing and interval between measurements (61 FR 36154 at 36184). FDA proposed that more frequent anthropometric measurements, especially early in the study, would enhance the study's ability to document physical growth changes by measuring growth during the most rapid, and thus, the most sensitive, phase of an infant's growth; this would increase the ability to place individual infants accurately in the correct percentile to track their growth patterns over time. In proposing the measurement schedule in § 106.97(a)(1)(i)(C), the Agency intended to have sufficient serial measurements for comparison between study groups and to derive reliable estimates of centile pattern growth and estimates of growth rates based on measurements over the entire study period. This proposed measurement schedule would accurately capture the curvilinear nature of infant growth and would provide sufficient data to interpret differences in growth and in growth rates, if differences exist.

Accordingly, FDA disagrees with the comment recommending fewer measurements in the early portion of a growth monitoring study. The approach recommended by this comment proposes only five measurements for the period between 14 and 112 days of age, with only two measurements proposed for the first 4 weeks of the study. Importantly, no data were submitted with this comment to support the adequacy of fewer measurements for evaluating the curvilinear nature of growth in young infants. As noted previously in this document, the most rapid phase of infant growth, and thus, the most sensitive period for detecting perturbations in growth, is the earliest weeks of an infant's life. Thus, it is critical that the anthropometric measurements be concentrated in this time period. As noted in this document, the interim final rule requires in § 106.96(b)(3) that anthropometric measurements be collected at the beginning of the study (maximum age of 2 weeks), 2 weeks into the study (maximum age of 4 weeks), and 4 weeks into the study (maximum age of 6 weeks), which will result in relatively more data from the earlier stages of an infant's life.

(Comment 235) One comment recommended that clinical studies of infants be conducted from 8 to 112 days of age with collection of anthropometric measurements at ages 8, 14, 28, and 42 days (±2 days) and at ages 56, 84, and 112 days (±4 days). This alternative schedule was recommended because, the comment asserted, it would match the measurement schedule of many reference (historical) data.

(Response) The alternative suggested in this comment would result in seven measurements over a roughly 15-week study period, with more frequent measurements during the early phase of the study, starting at 8 days of age. However, as discussed previously in this document, the Agency is establishing 14 days as the maximum age of enrollment to provide flexibility to foster recruitment of infants. Therefore, FDA is not persuaded by the information provided in the comment that the interim final rule should require enrollment by 8 days of age.

FDA's concerns with the use of historical data as controls are addressed previously in this document in the response to Comment 208. FDA agrees that some degree of flexibility in the timing of the serial measurements throughout the study is a reasonable design feature for the growth monitoring study. Thus, the interim final rule requires that, over the minimum 15 week study period needed to assess whether an infant formula supports normal physical growth, anthropometric measurements shall be made at the beginning and end of the study, with three of the six total measurements made within the first 4 weeks of the study and three measurements made at approximately 4-week intervals over the remaining 11 weeks of the study. Therefore, proposed § 106.97(a)(1)(i)(C) is renumbered as § 106.96(b)(3) in the interim final rule and is revised to require the growth monitoring study of normal physical growth include "anthropometric measurements made at the beginning and end of the study, and at least four additional measurements made at intermediate time points, with three of the six total measurements made during the first 4 weeks of the study and three measurements made at approximately four-week intervals over the remaining 11 weeks of the study."

To ensure the detection of biologically significant differences between test and control groups, if they exist, it is important that investigators make a diligent effort to take anthropometric measurements on infants consuming the test formula at the same ages as the measurements for the concurrent or historical control groups. FDA recognizes that investigators may not always be able to collect clinical data on all infants on the same day of age. FDA plans to address this need for flexibility while maintaining the scientific integrity of the study in future guidance.

d. *Comparison of anthropometric data.*

As noted previously in this document, in 1996, FDA proposed to require that anthropometric data collected during a growth monitoring study be plotted on the 1977 NCHS reference percentile body weight and length curves and proposed to incorporate by reference the 1977 NCHS growth charts. The Agency subsequently requested comment on whether certain Iowa data should serve as the comparison for anthropometric data collected during a growth monitoring study.

FDA received a number of comments on the collection and comparison of anthropometric data in a growth monitoring study. The Agency responds to those comments in this document.

(Comment 236) One comment stated that, in general, the use of growth curves and historical databases are considered references, not standards.

(Response) FDA agrees in part with this comment, which reflects the information available at the time of the two comment period reopenings. Until the WHO growth standards, upon which the 2009 CDC growth charts are based, became available, growth charts (including the 2000 CDC charts) were references that reflect how children in the United States have grown, and were not a standard of how children *should* grow.

The Agency believes, however, that this comment misunderstood FDA's use of the term "standard" in the 2003 reopening. In the 2003 reopening notice, the Agency requested comment on whether the Iowa reference data "should be the standard for clinical growth data rather than the NCHS growth charts (68 FR 22341 at 22342–22343)." In this instance, FDA intended the term "standard" to refer to a set approach of data evaluation and not to describe the growth charts.

(Comment 237) One comment suggested that new formulations of infant formula be tested by comparison to a control group of the same population receiving an appropriate control formula, rather than by comparison with standard curves, in accordance with proposed § 106.97(a)(1)(i)(B), because the curves are not considered accurate for all ethnic groups.

(Response) FDA believes that this comment did not fully understand the requirements of the proposed rule because the proposed rule would have required, and this interim final rule requires, that the growth monitoring study be an adequate and well-controlled study, which includes concurrent controls. (The issue of concurrent versus historical controls is addressed previously in this document in section VIII.C.3.a. As noted in that discussion, a manufacturer that wishes to use historical controls in a growth monitoring study may request an exemption under § 106.96(c)(2)(i) of the interim final rule to do so.) FDA notes that the use of historic controls may be problematic because the current study population would need to be matched to the historic controls, which may not be possible. Thus, the anthropometric data collected in a growth monitoring study will be required to be compared to a concurrent control group as well as to the standard reference data in the 2009 CDC growth charts.

FDA also notes that although the comment asserts that an appropriate concurrent control group needs to be composed of the "same population" as the infants consuming the test formula, the comment neither elaborates on the "same population" concept nor provides data or other information to support its assertion. Indeed, a clinical investigation is "well-controlled" only if the control group is appropriate to the purpose of the study. Thus, FDA expects that the report of a growth monitoring study will address the appropriateness of the selected control group. In addition, the interim final rule's requirement to use the 2009 CDC growth charts will address the concern expressed by this comment because, as discussed previously in this document, the WHO growth charts are based on data from six countries from different parts of the globe.

(Comment 238) One comment asserted that plotting anthropometric data from a growth monitoring study on CDC "growth" charts contributes little to the evaluation of the results.

(Response) FDA disagrees with this comment. Given the timing of the submission of this comment, the commenter is likely referencing the 2000 CDC growth charts. In 1996, FDA proposed that the anthropometric data collected during a growth monitoring study be compared to standard measurements of infant physical growth as a means of assessing whether the pattern of changes in weight and length of each individual infant study participant (both on test and control formulas) was similar to that observed for healthy infants of the same age, allowing for the range of normal individual variation in body weight and length that the 2000 CDC growth chart percentiles would have provided. Importantly, FDA does not intend that comparison with any growth chart be the sole analysis of the anthropometric data collected during a growth monitoring study. This comparison of the study data with growth charts will complement the comparison of data from the two study groups and will provide a context for interpreting the primary comparison of growth data between test and control groups.

In addition, by evaluating whether, over time, each infant study subject follows the generally expected growth rate for infants, deviations in individual growth rate may be identified, thereby alerting study investigators and FDA to a possible problem with formula sufficiency. The Agency expects that such deviations would be promptly scrutinized by study investigators to determine whether the deviations are likely to be formula-related. Thus, individual subjects' growth during the study may provide an early indication to investigators that the new formulation of an infant formula is not nutritionally sufficient. Also, monitoring individual infant rate of growth and comparing such growth rate to the 2009 CDC growth charts, which establish a standard for how infants should grow, may alert the study investigator to an individual infant who may be in distress or otherwise has potential issues and thereby, ensures the safety and well-being of the study subjects. Accordingly, for two separate reasons, it is important to compare each individual infant's growth to the 2009 CDC growth charts to monitor individual infant growth patterns.

(Comment 239) One comment challenged the use of individual growth charts, asserting that such charts are not appropriate to establish whether one group of infants differs from another group of infants in terms of growth rates. The comment further asserted that the use of curves to evaluate growth of infants could lead to inappropriate conclusions concerning normal growth, and cited a 2002 paper by Grummer-Strawn in support (Ref. 72).

(Response) FDA regards growth monitoring as the single most useful tool in describing health and nutritional status at both the individual and group level. Plotting the mean group data on a growth chart permits a comparison of how groups of infants grow. In contrast, as described previously in this document, plotting the growth of individual infants on growth charts provides an early indication of a possible problem with formula composition because it allows the investigator to observe disturbances in the growth of individual subjects.

FDA agrees that growth charts based on reference data have limitations, many of which have been addressed in the development of the 2009 CDC growth charts. As discussed previously in this document, the purpose of

plotting the anthropometric data of study subjects is to monitor individual subjects' growth during the study. Under § 106.96(b)(4) of the interim final rule, the growth monitoring study must include a concurrent control group, and the anthropometric data on the test and control groups will be separately compared independent of the growth chart activity to determine whether the new formula supports normal physical growth. Comparing the anthropometric data to a growth chart is intended to complement the use of concurrent controls and evaluation of the data from such controls.

The 2002 paper by Grummer-Strawn does not contradict the interim final rule's use of the 2009 CDC growth charts as a complement to the use of a concurrent control group (Ref. 72). The Grummer-Strawn paper explained why the use of the 2009 CDC growth charts is preferred to the use of the 2000 CDC growth charts. Unlike the 2000 CDC growth charts, the 2009 CDC growth charts are based on data from a longitudinal study of healthy infants growing optimally.

(Comment 240) One comment asserted that the use of curves to evaluate growth of infants could lead to inappropriate conclusions concerning normal growth.

(Response) FDA disagrees with this comment and notes that the comment did not explain how the complementary use of growth charts could result in inappropriate conclusions about growth. As noted, there is a two-fold purpose for plotting study subjects' individual growth data on a growth chart. FDA is requiring the plotting of these data as a check on the nutrition provided to both the test and control subjects and also to monitor the growth of individual study participants as part of the controls for human subject protection. The growth monitoring study must include a concurrent control group for which anthropometric data will be collected, analyzed, and used as a comparison to similar data collected from the infants on test formula.

(Comment 241) One comment stated that because the NCHS growth charts had been recently revised and published by the CDC in 2000, and because new science is constantly accumulating, which may impact the understanding of what constitutes "expected" physical growth, it would be shortsighted to tie the assessment only to the currently existing reference standards.

(Response) As discussed previously in this document, the CDC now recommends the use of the 2009 CDC growth charts that are based on the WHO Child Growth Standards for infants and children from birth to 24 months. To the extent that the CDC growth charts are revised in the future, and new growth charts are developed, FDA would consider the need to revise the growth charts required by this interim final rule at that time.

(Comment 242) One comment stated that the Iowa reference data, while excellent, may be less accessible than the NCHS growth charts, and the growth charts do incorporate some mechanism for quantitative assessment of growth patterns.

(Response) Data quality and not data accessibility is the relevant issue here. Although the Iowa reference data have some value (Refs. 68 and 73), the value of these reference data has been superseded by the 2009 CDC growth charts (Ref. 11). The Iowa data lack the ethnic and racial diversity that underlie the 2009 CDC growth charts. Also, the 2009 CDC growth charts establish a standard for the quantitative assessment of infant growth patterns. Given these strengths of the data provided in the WHO Child Growth Standards, § 106.96(b)(4) of the interim final rule requires that the anthropometric data be plotted on the 2009 CDC growth charts that are based on the WHO Child Growth Standards. A manufacturer who wishes to compare such data to other reference data, such as the Iowa reference data, must request and meet the requirements for an exemption under § 106.96(c)(2)(i) of the interim final rule.

(Comment 243) One comment stated that national data that reflect the diversity of the U.S. population should be used instead of the Iowa data, because Iowa has historically not represented diverse populations.

(Response) As discussed previously in this document, the 2009 CDC growth charts reflect appropriate racial and ethnic diversity and thus, are appropriate for plotting the growth of infants in the U.S. population.

(Comment 244) One comment recommended that for growth monitoring studies conducted outside the United States, the comparisons of anthropometric data should be plotted on growth charts that are routinely used in the country in which the study is performed.

(Response) Although the 1996 proposed rule did not specifically address the conduct of growth monitoring studies outside the United States, the Agency does not disagree that such studies may potentially be used as assurances for the quality factor of normal physical growth. Importantly, however, any such study would have to meet the requirements of the interim final rule, including the human subject protections for pediatric studies in 21 CFR part 50, subpart D, and 21 CFR part 56 to ensure that the infant study subjects are not inappropriately exposed to risk. When assessing the adequacy of a growth monitoring study conducted in a foreign country, FDA would consider whether the study satisfies good clinical practice, whether the investigators have recognized competence to conduct the study, whether the scientific evidence is valid, and whether the results are applicable to the U.S. infant population (Ref. 74). FDA would also consider whether the formula studied is the formula to be marketed in the United States. If the studied formula is not the formula to be marketed in the United States, the manufacturer would be required to request and meet the requirements for an exemption under § 106.96(c)(2)(i) of the interim final rule, and would be expected to explain why the formulation studied would be considered an appropriate proxy for the formula to be marketed in the United States.

In terms of the comment's specific concern, FDA notes that, as of March 2012, more than 140 countries had adopted the WHO Child Growth Standards. Thus, it is very likely that the WHO Child Growth Standards would be used in the foreign country in which a growth monitoring study is to be conducted, and such data would be consistent with the 2009 CDC growth charts.

(Comment 245) One comment urged that that studies conducted to evaluate infant growth test a sufficient number of infants to provide precise estimates of mean growth in weight, length, and head circumference (with confidence intervals around the mean that exclude rates of growth that are outside the bounds of accepted standards.)

(Response) FDA notes that the comment did not identify "accepted standards" or describe what would be considered "outside the bounds" of such standards.

Nonetheless, FDA agrees that a growth study must include a sample size sufficient to permit detection of differences in growth, between the control and test formula groups, if such differences exist. Confidence intervals are used in statistics to describe a range of values in an attempt to quantify the uncertainty of a particular statistical estimate. A narrow confidence interval suggests a highly precise estimate, and a wide confidence interval implies poor precision. The desired confidence interval can be used to estimate needed sample size as can a "power" calculation, and a wide confidence

interval is often an indication of inadequate sample size. Absent an adequate sample size, a study cannot sufficiently test the question under study. Although FDA is not codifying statistical requirements for a growth monitoring study, the Agency notes that such study must be appropriately designed and conducted so as to produce data that can be meaningfully interpreted on the question of whether the formula supports normal physical growth.

(Comment 246) One comment noted that because sick infants may grow at a slower rate and on lower percentiles due to their underlying medical condition rather than any deficiency in the formula being consumed, population reference standards are less useful for evaluating growth of sick infants than that of healthy infants.

(Response) FDA is uncertain as to what the comment meant by "sick infants." Although the Agency would agree that, generally speaking, due to an underlying medical condition, a sick infant will grow at a slower rate and on lower percentiles, FDA would not expect a manufacturer to plan purposefully to conduct a growth monitoring study in a population of "sick infants."

It is possible that the comment had in mind a growth monitoring study of a so-called "exempt infant formula." Section 412(h)(1) of the FD&C Act exempts certain infant formulas (those for infants with inborn errors of metabolism, low birth weight, or other unusual medical or dietary problems) from several statutory requirements, including the requirement that a manufacturer provide assurances that a formula meets the quality factor requirements established by the Secretary. Infants for whom "exempt infant formulas" are developed could be considered "sick." Importantly, however, as noted earlier in this preamble, this interim final rule applies only to nonexempt infant formulas. Thus, the manufacturer of an exempt infant formula is not required to comply with the requirement to conduct a growth monitoring study. FDA's current thinking on the application of the interim final rule to exempt infant formula may be found in a draft FDA guidance document, a notice of availability for which is published elsewhere in this issue of the **Federal Register**. Accordingly, the comment about growth rates of "sick infants" has no bearing on the interim final rule.

D. Exemptions From Quality Factor Requirements for Normal Physical Growth

In the 1996 proposed rule, FDA set forth in proposed § 106.97(a)(2) exemptions from the growth monitoring study requirements of proposed § 106.97(a)(1). Specifically, proposed § 106.97(a)(2) provided exemptions from the need for a study to evaluate physical growth in the following three situations:

- The manufacturer has similar experience using an ingredient, an ingredient mixture, or a processing method in the production of an infant formula marketed in the United States and can demonstrate that infant formula made with that ingredient, ingredient mixture, or processing method meets quality factor requirements in § 106.96;
- The manufacturer markets a formulation in more than one form (e.g., liquid and powdered forms) and can demonstrate that the quality factor requirements are met by the form of the formula that is processed using the method that has the greatest potential for adversely affecting nutrient content and bioavailability; and
- The manufacturer can demonstrate that the requirements (of § 106.97(a)(1)) are not appropriate for the evaluation of a specific infant formula, and that an alternative method or study design for showing that the formula supports healthy growth in infants fed it as their sole source of nutrition is available.

Several comments expressed confusion about the proposed exemptions. In response to these comments, FDA has significantly revised the proposed exemptions, which are set out in § 106.96(c) of the interim final rule. FDA's responses to the comments and the Agency's explanation for the revisions of the proposed exemptions are set out in this document.

(Comment 247) One comment recommended that a manufacturer be responsible for demonstrating that a growth study is not needed rather than exempting the manufacturer from conducting studies in a finite number of circumstances.

(Response) FDA agrees that, in general, a manufacturer should be responsible for demonstrating, in appropriate circumstances, that a growth study is not needed and that some "major changes" may not require a growth monitoring study to demonstrate that the formula supports normal physical growth. Thus, in the interim final rule, § 106.96(c)(1) contains a narrowly defined circumstance in which FDA will grant a manufacturer an exemption from the growth monitoring study requirement upon the manufacturer's request. The interim final rule's three additional exemptions from the requirement to meet the specific growth monitoring study requirements under § 106.96(b) clearly place the responsibility on the manufacturer to demonstrate to the Agency's satisfaction that the conditions of the exemption have been satisfied.

(Comment 248) Another comment stated that not every change in an infant formula raises questions as to infant growth that cannot be answered adequately by other scientific supportive data that may be equally convincing and more appropriate.

(Response) FDA agrees with this comment to the extent that it asserts that not every change in an infant formula will require the manufacturer to conduct a growth monitoring study of a new formulation of an infant formula. As noted in the response to the previous comment, the interim final rule provides separate exemptions from the growth monitoring study requirement in § 106.96(c)(2) of the interim final rule, including an exemption for the situation in which a manufacturer establishes that an alternative method or study design that is based on sound scientific principles can show that the formula supports normal physical growth when fed as the sole source of nutrition (§ 106.96(c)(2)(i) of the interim final rule). Thus, FDA believes that the interim final rule responds to this comment.

(Comment 249) One comment noted that the proposed rule contains a broad definition of "major change" that would mandate the filing of a premarket notification for numerous changes in processing or formulation, and that, while the industry recognizes that a growth study may be needed to assess some of these major changes (such as the use of certain new ingredients with no prior history of use in infant formula), there is no scientific basis to mandate a growth study for other major changes (such as the manufacture of an infant formula on a new processing line).

(Response) FDA disagrees with this comment to the extent that it asserts that the proposed definition of "major change" is too broad. The definition of "major change" in this interim final rule is discussed previously in this document in section IV.C.2.

FDA agrees that a growth monitoring study may be needed to assess some major changes (such as the use of certain new ingredients with no prior history of use in infant formula). However, in the case of use of a new processing line, some changes, such as

introduction of a new retort system with altered time and temperature processing conditions, could potentially have an adverse effect on the bioavailability of the formula, including the bioavailability of nutrients in the formula. On the other hand, FDA also recognizes that not all processing changes have the same potential to affect formula bioavailability and bioavailability of nutrients. Thus, § 106.96(c)(2)(ii) of the interim final rule provides an exemption from the quality factor requirements for normal physical growth, § 106.96(b) of the interim final rule, where the manufacturer provides assurances, as required under § 106.121 of the interim final rule, that demonstrate that a "major change" to an existing formula does not affect the bioavailability of the formula, including the bioavailability of nutrients in such formula. In addition, the interim final rule provides an exemption, upon the manufacturer's request, from the requirements of § 106.96(b) of the interim final rule, for a change that is a "major change," but is limited to altering the type of packaging of an existing infant formula. For these reasons, FDA declines to make revisions in response to this comment.

(Comment 250) One comment requested deletion of proposed § 106.97(a)(2)(i) because, the comment asserted, providing that an exemption "may be available" based on a requirement to "demonstrate" that a manufacturer or responsible party has experience with an ingredient, ingredient mixture, or a processing method constitutes premarket approval, not notification.

(Response) FDA disagrees with this comment to the extent that it asserts that the structure of proposed § 106.97(a)(2)(i) constitutes premarket approval. The proposed exemption is part of FDA's establishment of requirements for quality factors, an action expressly required by section 412(b)(1) of the FD&C Act, and nothing in this proposed exemption can or does alter the statutory process of premarket notification established by section 412(c) of the FD&C Act. FDA is deleting this specific exemption as unnecessary, however, because its specific circumstances are covered by the broader exemption in § 106.96(c)(2)(ii) of the interim final rule.

(Comment 251) One comment suggested that "similar experience" with an ingredient, an ingredient mixture, or a processing method should be relevant regardless of whether it occurred in the United States or elsewhere.

(Response) As noted, FDA is deleting the specific exemption in proposed § 106.97(a)(2)(i) because its circumstances will be covered by the broader exemption in § 106.96(c)(2)(ii) of the interim final rule. As part of the showing required by § 106.96(c)(2)(ii) of the interim final rule, a manufacturer may submit data from marketing outside the United States. FDA expects that, in such circumstances, the manufacturer will explain why such data are both relevant to a change in an infant formula marketed in the United States and why FDA should consider such data. Thus, under the interim final rule, the information relating to a manufacturer's experience outside the United States with an ingredient, ingredient mixture, or processing method will not be categorically classified as irrelevant to a change in a formula distributed in the United States.

(Comment 252) One comment requested deletion of § 106.97(a)(2)(ii) from the final rule but did not state why. Another comment agreed with the concept of choosing the most stringent case for conducting quality factor testing, whenever possible, but also stated that the choice of the representative formula should not be based solely on greatest adverse nutrient effect and provided the following example: If a product has two forms, one a liquid, ready-to-feed formula for hospital use only, and the other a powder formula for retail use, it may be more appropriate to study the form that is intended for long term use (i.e., the powder) as opposed to the very short term formula (i.e., the liquid), where processing actually may have the greatest adverse nutrient effect.

(Response) FDA disagrees with this comment. All forms of infant formula (ready-to-feed, concentrate, and powder) are marketed for extended use and thus, all must be capable of supporting normal physical growth of healthy term infants when used as the sole source of nutrition. For this reason, FDA disputes the comment's suggestion that powdered infant formula is the infant formula form intended for long-term use and thus, is the form that should be used in a growth monitoring study. The comment did not directly dispute FDA's view that the infant formula form processed under the most severe conditions is the form with the greatest likelihood of having adverse effects on its nutrient content and, thus, on the formula's bioavailability to the infant. In most cases, the most highly processed form of formula is the liquid product that undergoes pasteurization plus a heat treatment (typically, retorting to temperatures of 244 °F) to ensure commercial sterility. Such retorting is more severe than the heat treatment applied during the production of powdered products, which typically involves only pasteurization plus a relatively milder heat treatment during spray drying (powder temperature reaching 110–175 °F at the dryer outlet) (Ref. 75).

For this reason, FDA concludes that, in all likelihood, it would be appropriate to test in a growth monitoring study the liquid form of an infant formula processed under the most severe conditions, which results would be applicable to the less highly processed powdered form of the formula. For companies producing only powdered infant formula, the appropriate formula to test would, of course, be the powdered form. Given the disparities in processing and the effects of processing, however, the results of a growth monitoring study of powdered product generally would not be evidence that more highly processed liquid forms of the formulation satisfy the quality factor of normal physical growth in healthy term infants.

(Comment 253) One comment asserted that in applying the exemption of proposed § 106.97(a)(2)(ii), the manufacturer must be given responsibility for determining the most representative form to test.

(Response) FDA notes that the exemption in proposed § 106.97(a)(2)(ii) has been recodified at § 106.96(c)(2)(iii) of the interim final rule.

FDA disagrees in part with this comment to the extent that the comment asserts that the manufacturer should be able to determine unilaterally which form of a formulation to test in a growth monitoring study. The provision in question is part of the assurances that a formula satisfies the requirements for quality factors, which requirements and assurances the statute authorizes FDA to establish. Although the statutory scheme does not require the Agency to establish exemptions from the assurances that such requirements are satisfied, FDA has determined, in its discretion, to do so. Accordingly, it is also within the Agency's discretion to establish the terms of such exemptions, including the requirement that a manufacturer must satisfy FDA that the conditions of an exemption exist.

Moreover, in this case, it is reasonable that a manufacturer establish, to the Agency's satisfaction, that the form of the formula tested in a growth monitoring study is the form processed using the method with the greatest potential for adverse effects on the nutrient content and bioavailability. This standard will provide the greatest

certainty that all forms of a formula will be nutritionally sufficient regardless of the means of processing. FDA does agree, however, that under this exemption, the manufacturer may initially choose which form of a formulation to test for such purposes, but when submitting its assurances to the Agency, the manufacturer must demonstrate that the form tested meets the standard in § 106.96(c)(2)(iii) of the interim final rule.

(Comment 254) One comment argued that when studies have already been carried out on a form of the product that meets neither criterion (i.e., a formula with greatest potential for an adverse effect on nutrients or a formula intended for long term use), but the new formulation cannot reasonably be expected to differ significantly from the formula in question in terms of nutrient levels or bioavailability, those studies should also be able to provide the basis for exemption from additional studies. The comment stated that to require duplicative studies on different forms of a product that do not differ significantly would be difficult to justify on an ethical basis.

(Response) As noted previously in this document, FDA has added an exemption to the interim final rule allowing manufacturers to request an exemption and provide assurances that demonstrate that an alternative method or study design that is based on sound scientific principles is available to show that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition. This would permit a manufacturer to submit data relating to a particular formulation and to demonstrate that, even if the formulation tested is not the most heavily processed, sound science principles support reliance on such data to demonstrate that all forms of the formulation satisfy the quality factor of normal physical growth. Thus, there is an option in the interim final rule for the manufacturer to request an exemption from the need for a growth monitoring study under the circumstances identified in the comment.

(Comment 255) One comment requested deletion of proposed § 106.97(a)(2)(iii), but did not state why. Another comment noted FDA's recognition of the flexibility necessary to accommodate evolution in clinical study design and suggested that consideration should be given to situations where formula is not intended as the sole source of nutrition.

(Response) The request to allow infant formulas to be tested other than as the sole source of nutrition was addressed previously in this document in section VIII.C.4.c. Consistent with this discussion, the Agency does not agree that "sole source of nutrition" should be removed from the language in the exemption.

FDA acknowledged in proposed § 106.97(a)(2)(iii) that it is possible to assure the Agency that an alternative method or study design may be appropriate for the evaluation of the ability of some infant formulas to support normal physical growth. Therefore, FDA is providing a mechanism whereby manufacturers may request an exemption from the growth monitoring study requirement and use an alternate method or study design to provide assurances of normal physical growth. Because questions about the adequacy of a study design or method may be varied and may raise unique questions about the ability of such method or design to generate data to demonstrate normal physical growth, FDA is requiring that the assurances, required under § 106.121 of the interim final rule for such an exemption, demonstrate that the alternative method or study design be based on sound scientific principles and show that the formula supports normal physical growth when the formula is the sole source of nutrition (see section X for further discussion on the assurances required by § 106.121 of the interim final rule). This exemption, as revised, is now § 106.96(c)(2)(i) of the interim final rule.

(Comment 256) One comment suggested that proposed § 106.97(a)(2) be revised to allow a manufacturer to request an exemption from the individual testing requirements of proposed § 106.97(a)(1) if the manufacturer has determined that a change in formulation or processing does not cause the formula to be adulterated under section 412(a) of the FD&C Act and provides to FDA the basis for this determination. The comment argued that without the suggested change, the proposed rule provides no exemptions for changes such as minor changes in ingredient levels, replacing one nutrient form with another, or insignificant changes in processing conditions. The comment argued that such changes would require a submission under proposed § 106.140, which includes assurances under proposed § 106.121. The comment asserted that it was not the Agency's intent or a correct interpretation of section 412(d)(3) of the FD&C Act to require clinical testing and protein efficiency ratio (PER) data for such minor changes.

(Response) FDA disagrees with this comment. The fact that the proposed rule would have required a quality factors submission complying with proposed § 106.121 is clear evidence of FDA's intent. This intent is consistent with the statute, which requires that a manufacturer of a new infant formula provide assurance that the formula meets quality factor requirements in a "before first processing" (BFP) submission made under section 412(d)(3) of the FD&C Act. In lieu of a growth monitoring study, the manufacturer may request an exemption under § 106.96(c)(2)(ii) of the interim final rule and provide the scientific basis to explain why the changes in the formula would not affect the bioavailability of the formula and its nutrients and submit the results of the nutrient testing on finished product required under § 106.91(a) of the interim final rule.

The comment misunderstood the intent of the requirements for growth monitoring studies. FDA does not intend to require a growth monitoring study for all changes to a formula. A BFP notification under section 412(d)(3) of the FD&C Act must be submitted when the manufacturer determines that a change in the formulation of the formula or a change in the processing of the formula "may affect whether the formula is adulterated" under section 412(a) of the FD&C Act, e.g., when there are questions about whether a formula provides nutrients required by section 412(i) of the FD&C Act, meets quality factor requirements, or is in compliance with CGMP and quality control procedures. The 1986 Guidelines Concerning Notification and Testing of Infant Formulas listed several examples of types of changes for BFPs, such as replacing certain nutrient forms with another form or adjustments in the quantity of a nutrient in a premix or individually added nutrient that results in a specification change for that nutrient in the finished product, or changes in time-temperature conditions of preheating during handling of bulk product that cannot reasonably be expected to cause an adverse impact on nutrient levels or nutrient availability.

E. Quality Factor: Protein Quality

In 1996, FDA proposed (§ 106.96(c)) protein of sufficient biological quality as a second quality factor for infant formula and stated that a formula must not only contain adequate amounts of protein but also protein in a form that can be utilized by infants. At that time, the Agency noted that protein quality depends on a number of factors and complex interactions, including

differences in the digestibility of proteins from different sources and on the processing method for the formula. FDA also observed that the nutritive value of protein depends upon the presence of all essential amino acids at levels and relative proportions that will support healthy growth and stated that this quality factor would require an evaluation of whether the formula contains the essential amino acids and total nitrogen in the amount and proportion to permit normal tissue and organ growth and development (61 FR 36154 at 36181). In proposed § 106.97(b)(1), FDA proposed to require that biological protein quality be established using the Protein Efficiency Ratio (PER) rat bioassay described in the Official Methods of AOAC International, which the Agency proposed to incorporate by reference (61 FR at 36215). In proposed § 106.97(b)(2), the proposed rule identified two situations in which the manufacturer could request an exemption from the PER assay requirement.

FDA received no general comments on the Agency's proposal to establish protein of sufficient biological quality as a quality factor for infant formula. As noted previously in this document, FDA is reorganizing and consolidating into § 106.96 of the interim final rule most of the content of proposed § 106.96 and proposed § 106.97 related to requirements for infant formula quality factors. Thus, in the absence of comments, § 106.96(e) of the interim final rule establishes a second infant formula quality factor, biological quality of protein sufficient to meet the protein requirements of infants. Accordingly, § 106.96(e) states the following: "An infant formula manufacturer shall meet the quality factor of sufficient biological quality of protein."

1. Methods for Determining Biological Quality of Protein in Infant Formulas

(Comment 257) One comment objected that the proposal specified a particular AOAC method for evaluating protein quality and stated that the biological quality of the protein in infant formula could be established with any AOAC approved method including the PER.

(Response) FDA disagrees with this comment. As noted, protein will be of sufficient quality only if it contains sufficient amounts of all amino acids essential for infants, is present in adequate amounts, and is present in a form that infants can utilize. In the 1996 proposed rule, the Agency explained that "A protein source may contain the necessary amino acids, but they may be in a form that the infant cannot digest and absorb. Furthermore, processing methods may alter the chemical nature of the protein source, possibly making the protein more resistant to digestion by the infant" (61 FR 36154 at 36187). FDA proposed the PER method because, unlike chemical measures of protein composition, PER provides an estimate of the bioavailability of the protein. The Agency notes that the comment did not offer specific objections to the PER method. Nor did the comment identify other official AOAC methods that could successfully evaluate the presence and bioavailability of protein in an infant formula. Accordingly, FDA is not modifying this provision in response to this comment.

(Comment 258) Several comments questioned whether the PER is the best method of determining the protein quality of an infant formula and whether measurements of protein status in the infant would be more appropriate.

(Response) FDA disagrees with these comments to the extent that they challenge the use of the PER method. The PER method uses an animal model and thus, will allow a manufacturer to assess an infant formula's protein quality before the formula is fed to infants in a growth monitoring study or otherwise. High quality proteins are easily digestible and contain all of the essential amino acids in amounts that humans require. As stated in the previous response, evaluating protein quality requires both measuring the amount present and the amount that is bioavailable. The PER permits a comparison of different protein sources (i.e., is the test protein better or worse than the control protein?). FDA is aware that the PER, although sensitive, is not specific. The PER method has limitations (as discussed in this document); however, FDA is not aware of any other available method to assess protein bioavailability, and no comment, including this one, identified any such method.

FDA notes that the Agency consulted with an expert panel established by the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB). The LSRO panel was asked about minimum and maximum levels of protein in infant formula and considered methods that measured protein quality but not protein bioavailability (Ref. 76). Although total protein (measurement of nitrogen) as well as amino acid patterns can now be measured and such measures may be appropriate for certain aspects of protein quality, chemical measures of this type do not address the protein's bioavailability. The ability to estimate protein bioavailability is the advantage of a biological test system such as the PER assay.

FDA is well aware of the limitations of the PER as these limitations have been known for many years (Refs. 77 and 78). A principal criticism of the PER is that it is highly correlated to weight gain but does not characterize the protein, rather it reflects the rate of weight gain of the rat consuming the test substance with the weight gain of a control group. The Agency acknowledges that body weight gain does not necessarily correspond to gain in muscle related to protein intake nor does body weight gain detect changes in body composition (Refs. 77 and 78). The PER assay has also been criticized because, even under standardized conditions, laboratories may obtain variable results in terms of the ratio percentage. However, PER is a simple test with an AOAC standardized method that has improved the assay (Ref. 79). Appropriate modifications of the PER are described in this document.

For the foregoing reasons, FDA declines to delete the requirement that infant formula protein be assayed using the PER method.

(Comment 259) One comment stated that when a manufacturer proposes to alter the protein source or composition of an infant formula, the manufacturer should be required to demonstrate that the serum amino acid levels of infants consuming the altered formula are comparable to those of breast-fed infants or infants fed other standard infant formulas.

Another comment countered that universally requiring amino acid determinations in infants consuming the altered infant formula would add nothing to the assessment of new combinations of protein sources and the potential for the use of additional invasive procedures to collect these data would be considered unethical unless specifically justified. The comment further stated that the need for such analyses can only be determined on a case-by-case basis.

(Response) Determining serum free amino acid levels in infants consuming the test formula would not be an adequate means of assessing protein quality. Importantly, the comment did not provide evidence to support this recommendation, and there are at least two reasons that such tests would have limited value, if any. First, serum free amino acids reflect circulating amino acids, which may be present in an infant's blood either from the diet (i.e., the infant formula being consumed) or from endogenous sources, such as the breakdown of the infant's muscles. In

addition, determining serum levels of free amino acids would require blood draws, an invasive procedure. Given the limited usefulness of serum free amino acid analyses, requiring such analyses and thus, an invasive procedure, is not reasonable. Accordingly, FDA declines to revise the interim final rule to require formula manufacturers to demonstrate routinely that serum amino acid levels of study infants are comparable to those of breast-fed infants or of infants fed other appropriate infant formulas.

(Comment 260) One comment disputed that PER measurements in young rats would add anything to the data collected in human infants. The comment asserted that anthropometric measures, nitrogen balance studies, and biochemical markers required by FDA in the growth monitoring study would provide an indication of the sufficiency of protein quality and quantity and that these measures in human infants would be sufficient to confirm that such quality and quantity are adequate.

(Response) FDA disagrees with this comment. Contrary to what some comments have suggested, FDA did not propose to require nitrogen balance studies or biochemical markers as requirements for infant formula quality factors. (A balance study is a study that measures each individual study subject's intake and excretion of one or more particular substances, such as required nutrients.)

Moreover, the PER analysis would contribute valuable information to the assessment of an infant formula's nutritional adequacy, value not provided by a growth monitoring study, for two reasons. First, as noted, the PER analysis is conducted in an animal model and thus, will permit determination of a formula's protein quality before infants are exposed to the formula. This ensures that infants will not be fed a formula with inadequate or biologically unavailable protein, which is critical because when an infant formula is the sole source of nutrition, any inadequacy in protein quality cannot be compensated for by other dietary components, and such inadequacy may result in serious, and in some cases, permanent, adverse effects on an infant's growth and development (Ref. 80).

Second, as discussed previously in this document, a growth monitoring study that includes anthropometric measurements assesses whether the complete infant formula matrix supports normal physical growth and contributes to an assessment of healthy growth. However, it is imperative that protein quality be established prior to its use in an infant formula, particularly where there is an accepted means (the PER) to do so. It is critical that the composition of the protein, e.g., type and amounts of essential amino acids, in a formula be adequate to support the needs of a developing infant, and that the formula containing the protein support normal physical growth. Importantly, the failure of a formula to support normal physical growth could be the result of a number of shortcomings in the formula. Thus, the growth monitoring study will not provide information specific to protein quality and bioavailability.

2. Method for Assessing Protein Efficiency Ratio (PER)

(Comment 261) One comment pointed out that the citation to the PER method in proposed § 106.97(b)(1) should be changed to Protein Efficiency Ratio (PER) rat bioassay described in the "Official Methods of Analysis of AOAC INTERNATIONAL," 16th ed., AOAC® Official Methods 960.48, Protein Efficiency Ratio Rat Bioassay and 982.30, Protein Efficiency Ratio, Calculation Method.

(Response) In § 106.96(f) of the interim final rule, FDA has updated the references to AOAC International and to the AOAC methods, and has used the current name and address for AOAC International in § 106.160, "Incorporation by reference."

(Comment 262) Another comment stated that proposed § 106.97(b)(1) should be revised to recognize other AOAC methods as they become available.

(Response) FDA will evaluate any AOAC method that becomes available that might serve as a substitute for, or alternative to, the PER assay and, if appropriate, will consider amending § 106.96(f) to include such method or methods.

Although FDA is not revising the requirement to use the PER assay in response to comments, the Agency is making, in addition to several minor editorial changes, three revisions to proposed § 106.97(b)(1) on its own initiative.

First, at the time of the 1996 proposal, certain language was inadvertently omitted from proposed § 106.97(b). In particular, the phrase by "an appropriate modification of" should have been included so that the sentence, as proposed, would read "The manufacturer shall establish the biological quality of the protein in its infant formula by demonstrating that the protein source supports adequate growth using an appropriate modification of the Protein Efficiency Ratio (PER) rat bioassay described in the "Official Methods of Analysis of the Association of Official Analytical Chemists . . . ." The basis for this change is explained in this document.

The requirement to assess the quality of the protein component of an infant formula was originally established in FDA's quality control regulations for infant formula, 21 CFR 106.30(c)(2), which were issued in 1982 (47 FR 17016 at 17026 (April 26, 1982)). Comments on the proposed rule asserted that, without certain modifications, the official AOAC assay for PER would not give valid test results for infant formulas due to the type of fat and concentrations of lactose and fat required in infant formula (47 FR 17016 at 17023). The Agency agreed with this view and thus, § 106.30(c)(2) of the final rule provided that "The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis."

The purpose of the PER rat bioassay is to compare the quality of protein in a finished infant formula product to a protein of known high biological quality (casein) to demonstrate that the protein in a proposed formula is bioavailable (supports comparable growth of the rats), as a decrease in the protein's biological value would not be detected by chemical analysis. As noted previously in this document, the PER rat bioassay is currently the only method that accounts for protein digestibility and absorption in a living animal system. Digestibility and absorption are critical elements to ensuring, prior to marketing, that an infant formula has sufficient protein quality.

The official AOAC method is based on weight gain in test animals where one group of rats is fed a casein control diet and another group is fed a diet containing the test product (infant formula) (Ref. 81), and the animals' food intake and body weight are measured. The mean protein efficiency ratio (PER) is calculated based on the protein consumed by and weight gain of each animal group. Prior to study initiation, the test product (finished infant formula) and the casein control are subjected to a compositional assessment (proximate analysis). The diets are then formulated to contain matching amounts of protein, fat, minerals, fiber, and moisture. These diets are analyzed for protein to confirm that they were formulated correctly, which information is used to calculate the PER at completion of the trial.

Although the method has limitations with respect to assessment of the quality of protein sources for infant formulas, the limitations are greatly reduced by modification of the test and control diets. Three dietary adjustments

commonly required for evaluation of the protein quality of infant formulas are:

- *Adjustment of the fat content:* In most cases, when the infant formula is incorporated into the protein evaluation diet based on the nitrogen content, the fat content will be above the limit (8 percent) specified by the AOAC Official Method. The fat content of the reference control (casein) diet must be adjusted to match the fat content of the infant formula test diet.
- *Carbohydrate composition adjustments:* Lactose is the carbohydrate component of most milk-based infant formulas. Rats do not tolerate lactose well and often develop diarrhea, which may lead to an underestimation of protein quality of the formula. The casein reference control diet(s) must contain levels of lactose comparable to the amount in the infant formula test diet to adjust for possible confounding of the estimation of protein quality. If an infant formula contains a carbohydrate source other than lactose (e.g., sucrose, corn syrup solids), the source of carbohydrate in the formula should be used in the control diet as well.
- *Removal of water from liquid infant formula:* Infant formula is incorporated into the protein evaluation diet based on its nitrogen content. Because of the high water content of infant formulas in liquid form, these products usually are below the lower limit of total nitrogen (1.8 percent by weight) required for the PER bioassay. Liquid infant formulas must be freeze-dried so that the test sample contains more than 1.8 percent nitrogen before the infant formula test diet is formulated.

Second, in order to ensure that determination of the biological quality of the protein of a new formulation precedes the initiation of the growth monitoring study required by § 106.96(b) of the interim final rule, the Agency is adding the following sentence in § 106.96(f) of the interim final rule: "The PER rat bioassay shall be conducted on a formula and the results evaluated prior to the initiation of a growth monitoring study of the formula that is required under paragraph (b)." This will prevent the exposure of growth monitoring study subjects to a protein of undetermined biological quality and any unnecessary attendant risk of such exposure.

Finally, proposed § 106.97(b)(1) provided that "[i]f the manufacturer is unable to conduct a PER rat bioassay because of the composition of the protein in the formula, then it shall demonstrate that the amino acid composition of the protein meets the known amino acid requirements of infants for whom the formula is intended." As an example of a formula for which this proposed flexibility might be necessary, the preamble cited the instance of an "exempt infant formula" that contains an incomplete protein (61 FR 36154 at 36187). As discussed previously in this document, this interim final rule only applies to non-exempt infant formulas; the composition of the protein of such non-exempt formulas would not preclude the use of the PER to determine protein quality. Therefore, FDA is excluding as unnecessary from § 106.96(f) of the interim final rule the following sentence:"If the manufacturer is unable to conduct a PER rat bioassay because of the composition of the protein in the formula, then it shall demonstrate that the amino acid composition of the protein meets the known amino acid requirements of infants for whom the formula is intended."

F. Exemption From the Quality Factor of Protein Quality Sufficiency

As noted, the 1996 proposed rule identified two situations in which the manufacturer could request an exemption from the PER assay requirement in proposed § 106.97(b)(2). Specifically, an exemption from the PER requirement would have been available where the manufacturer was already using the same protein source produced by the same processing method in another infant formula marketed in the United States, and the manufacturer could demonstrate that current formula met the quality factor requirements of the proposed rule, and where the protein source, including any processing method used to produce the protein, would not have been a major change from its predecessor formula and the manufacturer could demonstrate that the predecessor formula met the quality factor requirements of the proposed rule.

As discussed previously in this document in section VIII.D. in this interim final rule, FDA is revising the exemptions from conducting a growth monitoring study under § 106.96(b). Section 106.96(c)(1) of the interim final rule provides that, in response to a manufacturer's request, the Agency will exempt the manufacturer from the obligation to conduct a growth monitoring study when the manufacturer requests an exemption and provides assurances under § 106.121 of the interim final rule that the changes to the existing formula are limited to changing the type of packaging for an existing infant formula.

An assay of protein quality would also not be required in the foregoing circumstance because the change would not be expected to have an effect on protein quality or on any of the other nutrients in the formula that could affect the bioavailability of the protein. Accordingly, § 106.96(g)(1) of the interim final rule provides that FDA will exempt a manufacturer from the requirement to conduct a PER assay where the manufacturer requests an exemption and provides assurances that the change to an existing infant formula is limited to changing the type of packaging for an existing formula.

FDA also recognizes that not all changes to an infant formula have the potential to affect the biological quality of the protein in the formula. Accordingly, to provide flexibility in the interim final rule for these types of circumstances, § 106.96(g)(2) of the interim final rule includes an additional exemption. FDA emphasizes that it is the obligation of the manufacturer to establish that all the conditions of the exemption are satisfied. Specifically, § 106.96(g)(2) of the interim final rule provides that a manufacturer may request an exemption from the requirement to perform the PER assay if the manufacturer demonstrates that a change made by the manufacturer to an existing formula does not affect the quality or the bioavailability of the protein.

G. Miscellaneous Comments on the Quality Factor for Sufficient Biological Quality of Protein

(Comment 263) In response to the 2003 reopening notice, one comment stated that protein quality for infant formula is based on estimates, extrapolations, and safety margins that have caused some products to provide protein intakes to formula-fed babies at twice the rate of breastfed infants. The comment stated that "Heat-treated proteins have lower digestibility with high amounts contributing to metabolic and excretory stress in the infant."

(Response) This comment appears to raise issues related to the quantity of protein in infant formulas rather than protein quality and did not suggest changes to the proposed quality factor of protein quality. The issue raised in this comment would be more appropriately considered in any future revision of § 107.100 and the maximum protein levels for infant formulas, an issue that is outside the scope of this interim final rule. Accordingly, no response to this comment is required.

H. Application of Quality Factors to Currently Marketed and Previously Marketed Formulas

As noted in section VIII.C.1, in 1996, FDA proposed "normal physical

growth" as a quality factor (proposed § 106.96(b)) and proposed requirements for the assurances for such quality factor (proposed § 106.97(a)). At the same time, FDA proposed "sufficient biological quality" of the formula's protein component as a second quality factor (proposed § 106.96(c)) and proposed requirements for the assurances for this quality factor (proposed § 106.97(b)). As proposed, the quality factors described in proposed § 106.96 and the assurance provisions of proposed § 106.97 would have applied to all infant formulas distributed in U.S. commerce and not simply "new infant formulas." Subsequently, in the 2003 reopening, the Agency expressly requested comment on the appropriateness of the two quality factors proposed in 1996 (68 FR 22341 at 22342–22343).

This interim final rule establishes two quality factors, the quality factor of "normal physical growth" (§ 106.96(a) of the interim final rule) and the quality factor of "sufficient biological quality of protein" (§ 106.96(e)), and sets minimum requirements for both quality factors (§ 106.96(b) and (f) of the interim final rule, respectively). Under the interim final rule, for each quality factor, the results of a single study, when conducted consistent with the requirements of the interim final rule, are sufficient to establish that the formula meets the quality factor. Thus, under the interim final rule, a single study—a growth monitoring study conducted as specified in § 106.96(b) of the interim final rule—is sufficient to demonstrate that an infant formula supports normal physical growth. Similarly, a single study—a protein efficiency ratio (PER) study conducted as specified in § 106.96(f) of the interim final rule—is sufficient to establish that a formula's protein component is of sufficient biological quality.

Like the proposed rule, the quality factors set forth in the provisions of § 106.96(a) and (e) of the interim final rule apply to all infant formulas distributed in interstate commerce. This means that a "not new" infant formula (i.e., an infant formula that previously was the subject of a new infant formula submission made under section 412(c)(1) of the FD&C Act) must satisfy the two quality factors established by this interim final rule. These "not new" infant formulas may be formulas that are not currently distributed as well as formulas that are currently distributed in the United States. Any formula, including a "not new" formula, that does not satisfy the quality factor requirements established under section 412(b)(1) of the FD&C Act is deemed adulterated under section 412(a)(2) of the FD&C Act.

As discussed in the introduction of this document, the 1986 amendments mandated that FDA establish by regulation requirements for quality factors for infant formula. Section 412(b)(1) of the FD&C Act, the quality factor requirements provision, is not self-executing and thus, there have been no enforceable quality factor requirements pending the issuance of this interim final rule. Prior to and since the 1986 amendments, a variety of infant formula products have been distributed in the United States. Consistent with section 412(c) and (d) of the FD&C Act, manufacturers of these products have been required to notify FDA of their intent to market these infant formulas and to make a new infant formula submission, and they have done so. In the absence of implementing regulations, however, these notifications were not required to provide assurances that the formula meets any quality factor requirements.

Nevertheless, many notifications made after publication of the 1996 proposed rule have included information about the ability of the infant formula that is the subject of the notification to support normal physical growth and about the protein quality. Several submissions have included growth information on the formula, some of which was derived from growth studies that conform, more or less, to the provisions in proposed § 106.97(a). Some submissions have also included evidence on the biological quality of the formula's protein component. Over this same period, as manufacturers have brought to market new products containing new ingredients, they have often stopped distributing previous versions of the newer products. Thus, there is an existing body of data and information, both published and unpublished, on many currently marketed and previously marketed formulas that may be relevant to whether such formulas support normal physical growth and whether the protein component of each such formula is of sufficient biological quality.

FDA evaluated the data and information available to the Agency that is relevant to whether currently marketed infant formulas meet the two quality factors established by the interim final rule. This information includes material submitted to FDA and also published studies. The Agency recognizes, however, that formula manufacturers may have information on their products in addition to that available to FDA. Importantly, none of the available evidence suggests that any currently marketed infant formula fails to support normal physical growth or uses a protein component that lacks sufficient biological quality. By the same token, however, the available scientific record evaluated by FDA did not include sufficient information to document that all currently marketed infant formulas meet the quality factors of normal physical growth and are composed of a protein of sufficient biological quality.

Although the data and information available to FDA may not be sufficient to demonstrate that every currently marketed formula meets the two quality factors, the Agency acknowledges that removal of infant formula from the market, based on limitations in the data and information that is available to FDA to date, would likely be very disruptive. Therefore, the Agency has developed separate provisions and an orderly process for these formulas to transition to the newly established requirements. There are two reasons that an orderly process that minimizes disruption in the marketplace is essential for a product like infant formula.

First, as noted previously in this document, for many infants, infant formula is the sole source or the primary source of nutrition in the critical early months of growth and development, and formula often continues to be an integral part of the diet of many infants through 12 months of age. Indeed, based on the CDC's study of breastfeeding rates in the U.S., in 2010, one quarter of U.S. infants were formula-fed from birth (approximately 1,027,000 infants) and by three months of age, two-thirds of U.S. infants (approximately 2,700,000 infants) relied on formula for some portion of their nutrition (*http://www.cdc.gov/breastfeeding/data/reportcard.htm*) (Ref. 82). Thus, it is essential that an adequate supply of formula be maintained as infant formula products transition to compliance with the requirements established by the interim final rule.

Disruption in the infant formula supply in the United States could be especially problematic for the USDA's Special Supplemental Nutrition Program for Woman, Infants, and Children (WIC). More than half of the infant formula fed to U.S. infants is purchased through the WIC program. This program provides Federal grants to states for supplemental foods, health care referrals, and nutrition education to low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are at nutritional risk. Under the current WIC program, each state contracts with a single formula

manufacturer to provide formula to the WIC participants in the state. Although it is possible for a state to change its contractual arrangements, it is nevertheless important to avoid market disruptions that could have an impact on the availability of formulas distributed through the WIC program.

Second, maintaining sufficient availability of a variety of infant formulas in the marketplace during this transition period is important. Although all infant formula products must satisfy the nutrient requirements of FDA's regulations in § 107.100, these products differ in their overall composition; such differences are not only in a formula's protein source (cow milk protein or soy protein isolate) but extend to other ingredients and components. The variations in formula products may not be equally tolerated by every infant and, thus, different infant formulas may not be interchangeable. For this reason, pediatricians generally recommend that parents of a formula-fed infant identify a single formula that their infant can tolerate and feed that formula to their child. Thus, it is also important to maintain a consistent supply of a variety of formula products.

As noted, there is a considerable body of evidence relevant to whether currently marketed and previously marketed infant formulas are likely to satisfy the quality factors established by the interim final rule. These data and information consist of a variety of different studies and sources of information. The studies may not, strictly speaking, fulfill the detailed requirements of the interim final rule in that, for example, there is not likely to be a single growth monitoring study that satisfies all of the requirements of § 106.96(b) of the interim final rule. Importantly, however, this existing body of evidence, when viewed *collectively,* may show that a particular infant formula supports normal physical growth. FDA further recognizes that if these existing data and this existing information were not considered in assessing currently marketed and previously marketed formulas, it would likely be necessary for formula manufacturers to conduct new growth monitoring studies on such formulas, which would require infant study subjects to be exposed to the risks, however small, of the study protocol. In contrast, considering the existing clinical evidence to assess whether a currently marketed or previously marketed formula supports normal physical growth may avoid exposing infants to these additional risks.

Going forward, infant formula manufacturers will be aware of the interim final rule's requirement for a growth monitoring study and the design characteristics required for such a study. Thus, the Agency fully expects that, in the future, the data and information used by a manufacturer to demonstrate that a new infant formula supports normal physical growth will conform to the specific requirements of § 106.96(b) of the interim final rule unless the formula qualifies for an exemption under § 106.96(c) of the interim final rule.

To minimize market disruption and its potential public health impact, and to limit the exposure of infants to the risks of additional clinical studies while ensuring that a formula meets the quality factors established in this interim final rule, the interim final rule includes specific provisions that apply to certain currently marketed and previously marketed formulas. The interim final rule designates these formulas as "eligible" infant formulas.

The following discussion explains § 106.96(i) of the interim final rule and specifically addresses: (1) Which formulas are covered by these provisions (2) the applicable standard for each quality factor and its basis, (3) the voluntary petition process and the outcome of a manufacturer's participation in the petition process, (4) records maintenance requirements, (5) the consequences of engaging or not engaging in the voluntary petition process, and (6) compliance dates.

The provisions of § 106.96(i) of the interim final rule apply to any infant formula that satisfies the definition of "eligible infant formula." An "eligible infant formula" is defined in § 106.3 of the interim final rule as an infant formula that "could have been or was lawfully distributed in the United States on May 12, 2014. Thus, any formula that has been the subject of a properly submitted infant formula notification under section 412(c) of the FD&C Act at least 1 day before the publication date of the interim final rule is eligible to utilize the provisions in § 106.96(i) of the interim final rule.

All infant formulas, including eligible infant formulas, must satisfy the two quality factors established by the interim final rule, normal physical growth and sufficient biological quality of the protein component of the formula. Section 106.96(i) of the interim final rule establishes quality factor requirements for eligible infant formulas. Although the requirements of § 106.96(i) of the interim final rule are somewhat more flexible than the interim final rule's quality factor requirements for infant formulas that are not "eligible" infant formulas, these requirements are substantial. In particular, each of the three alternative means of demonstrating quality factor satisfaction mandates that scientific evidence be used to demonstrate that the formula meets the quality factors. Moreover, under § 106.96(i)(4) of the interim final rule, the manufacturer of each eligible infant formula is required to make and retain records to substantiate the view that the formula meets the quality factors, and such records must contain all relevant scientific data and information relied upon by the manufacturer for such substantiation as well as a narrative explanation of the manufacturer's conclusion.

It is reasonable to extend the provisions in § 106.96(i) and its more flexible standards to formulas that are lawfully marketed by the 89th day after the publication date of this interim final rule because these are the formulas currently fulfilling the needs of formula-fed infants. Establishing a mechanism to facilitate their continued availability and thus, to minimize disruptions in the availability of this essential source of infant nutrition, is imperative. It is also sound to extend these provisions only to those formulas that may be lawfully marketed by the 89th day after the publication of this interim final rule. With the publication of this interim final rule, infant formula manufacturers are now fully aware of the standards that its products must satisfy and thereby, are positioned to develop the required data and information for any new infant formula that is the subject of a submission under section 412(c) of the FD&C Act, including information that satisfies § 106.96(b) and (f) of the interim final rule. By comparison, a manufacturer of an eligible infant formula could not reasonably have been expected to develop the data and information to fulfill the specific requirements of § 106.96(b) and (f) of the interim final rule.

Section 106.96(i)(1) of the interim final rule addresses the quality factor of normal physical growth. Under this provision, an "eligible infant formula" that fulfills one or more of three criteria meets the quality factor of normal physical growth. FDA recognizes that there may be one or more eligible infant formulas for which no growth monitoring studies may have been conducted. In such circumstances, FDA recommends that the manufacturer conduct a growth monitoring study and may choose to design and conduct the study in conformity with the primary quality factor requirements of the interim final rule in § 106.96(b). Thus, § 106.96(i)(1)(i) of the interim final rule

provides that an eligible infant formula meets the quality factor of normal physical growth if the scientific evidence on such formula fulfills the requirements of § 106.96(b) of the interim final rule. Similarly, a manufacturer who previously chose to develop evidence of a formula's ability to support normal physical growth may have, quite reasonably, chosen to conduct a growth monitoring study, the design of which conformed to the provisions proposed in 1996 as those proposed provisions represented FDA's then-best judgment about the design and conduct of a growth monitoring study. To provide for these circumstances, the Agency has set forth in § 106.96(i)(1)(ii) of the interim final rule the requirements for a growth monitoring study that were proposed in 1996, and § 106.96(i)(1)(ii) of the interim final rule states that an eligible infant formula meets the quality factor of normal physical growth if the scientific evidence on such formula meets the provisions of that paragraph. The growth charts that the 1996 proposed rule stated should be used for plotting growth data are incorporated by reference under § 106.160 of the interim final rule. Finally, there may be some eligible infant formulas for which there is no single growth study satisfying § 106.96(i)(1)(i) or (i)(1)(ii) of the interim final rule but for which there is a body of scientific evidence drawn from multiple sources that, taken as a whole, demonstrates that the formula supports normal physical growth. Thus, § 106.96(i)(1)(iii) of the interim final rule provides that an eligible infant formula meets the quality factor of normal physical growth if the scientific evidence on such formula otherwise demonstrates that the formula supports normal physical growth. This third option will require FDA to exercise its scientific judgment about the data and other information and whether that evidence demonstrates that the formula supports normal physical growth.

Section 106.96(i)(2) of the interim final rule addresses the quality factor of sufficient biological quality of a formula's protein component. Under this provision, an "eligible infant formula" that fulfills one or more of three criteria meets the quality factor of sufficient biological quality of the protein component. FDA recognizes that there may be eligible infant formulas for which a protein efficiency ratio (PER) study was not conducted. The manufacturer may choose to conduct a PER study as specified in § 106.96(f) of the interim final rule. Thus, § 106.96(i)(2)(i) of the interim final rule provides that an eligible infant formula satisfies the quality factor of sufficient biological quality of the protein component if the scientific evidence on such formula fulfills the requirements of § 106.96(f) of the interim final rule. Similarly, a manufacturer who previously chose to develop evidence of the sufficient biological quality of a formula's protein component may have, quite reasonably, chosen to conduct a PER study according to the proposed rule's provisions. To provide for these circumstances, the Agency has set forth in § 106.96(i)(2)(ii) of the interim final rule the requirements for establishing sufficient biological quality of a formula's protein component that were proposed in 1996, and § 106.96(i)(2)(ii) of the interim final rule states that an eligible infant formula meets the quality factor of sufficient biological quality of the protein component if the scientific evidence on such formula meets the provisions of that paragraph. The official method of analysis of AOAC to conduct a PER study that was proposed in the 1996 proposed rule is incorporated by reference in § 106.160 of the interim final rule. Finally, there are some eligible infant formulas for which there may be a body of scientific evidence drawn from multiple sources that, taken collectively, demonstrates that the formula's protein component is of sufficient biological quality. Thus, § 106.96(i)(2)(iii) of the interim final rule provides that an eligible infant formula satisfies the quality factor of sufficient biological quality of the protein component if the scientific evidence on such formula otherwise demonstrates that the protein component of the formula has sufficient biological quality. Like § 106.96(i)(1)(iii) of the interim final rule, this third option will require FDA to exercise its scientific judgment about the data and other information and whether that evidence demonstrates that the protein component of the formula is of sufficient biological quality.

An infant formula, including a "not new" infant formula, that does not comply with established quality factor requirements is deemed adulterated under section 412(a)(2) of the FD&C Act. As an adulterated food, this formula is subject to seizure, condemnation, and forfeiture under section 304 of the FD&C Act. Similarly, those who ship the formula in interstate commerce, cause its interstate shipment, or commit another prohibited act related to an adulterated food may be enjoined under sections 301 and 302 of the FD&C Act.

FDA recognizes that to facilitate marketing and distribution plans, a manufacturer of an eligible infant formula may wish to understand the Agency's assessment of the quality factor evidence for that formula. To permit the manufacturer of an eligible infant formula to be aware of FDA's view of the manufacturer's determination that their formula meets the quality factor requirements of § 106.96 of the interim final rule prior to the compliance date for meeting the requirements under 106.96(i), § 106.96(i)(3) of the interim final rule includes a time-limited petition process that allows a manufacturer to submit a citizen petition to FDA that contains scientific data and information to demonstrate that an eligible formula supports normal physical growth, that the formula's protein component is of sufficient biological quality, or both. FDA emphasizes that although participation in the petition process established by § 106.96(i)(3) of the interim final rule is voluntary, satisfying the two quality factor requirements of the interim final rule is required of all infant formulas distributed in interstate commerce. The Agency encourages any manufacturer planning to file a petition under § 106.96(i)(3) of the interim final rule to contact FDA to discuss any questions.

The procedure in § 106.96(i)(3) of the interim final rule uses the FDA citizen petition process in 21 CFR 10.30, and allows such a petition for an eligible formula to be submitted untilNovember 12, 2015. Although there is likely to be some existing scientific evidence relating to quality factor status of many eligible formulas, some manufacturers may need to design, conduct, and analyze the results of a growth monitoring study before they can make a submission to FDA through the voluntary petition process. Because the Agency recognizes that one or more manufacturers of eligible infant formulas may need to design, conduct, and analyze the results of a growth monitoring study to develop evidence of the formula's ability to support normal physical growth, the interim final rule establishes a separate compliance date for certain quality factor provisions that apply to eligible infant formulas. Specifically, §§ 106.96(a), 106.96(e), 106.96(i)(5), 106.100(p)(2) and 106.100(q)(2) of the interim final rule are binding as of November 12, 2015. This means that eligible infant formulas must meet the quality factors, and keep records demonstrating that they meet the quality factors, as of November 12, 2015. Postponing the compliance date for these provisions for eligible infant formulas, combined with the same nearly 2-year period to submit a

voluntary petition will provide manufacturers of eligible infant formulas with sufficient time to develop the required data and information to demonstrate that their products meet the quality factors, and to submit such data and information to FDA through the voluntary petition process.

FDA notes that under current Agency regulations and practice, a response to a citizen petition is publicly available and is routinely posted on the Agency's Web site. The Agency intends to follow this practice for infant formula quality factor citizen petitions and FDA's responses to such petitions by establishing a Web page dedicated to such petitions and responses. This practice will allow the public, including competitors, purchasers for retailer stores, and individual consumers, to know whether the manufacturer of an eligible infant formula product has availed itself of the opportunity to demonstrate that the formula meets the quality factors of normal physical growth and sufficient quality of the protein and to be informed of FDA's response to such submission.

The petition process in § 106.96(i)(3) of the interim final rule is a voluntary process, one that will provide FDA with access to important information relating to eligible infant formulas. For infant formula manufacturers and other interested parties, this process has the advantage of clarity and certainty in terms of whether FDA views a formula to be in compliance with the relevant quality factor requirements. Likewise, infant formula purchasers at all levels of the supply chain will indirectly benefit from this process because they will have access to scientific evidence and other information on the quality factor status of eligible infant formulas as well as FDA's view of that evidence.

Accordingly, under § 106.96(i)(3) of the interim final rule, the manufacturer of an eligible infant formula may, not later than November 12, 2015, submit a citizen petition to FDA under 21 CFR 10.30 that such formula fulfills one or more of the criteria in § 106.96(i)(1) of the interim final rule relating to the quality factor of normal physical growth, one or more of the criteria in § 106.96(i)(2) of the interim final rule relating to the quality factor of sufficient biological quality of the protein component, or both. Consistent with the citizen petition regulation, § 10.30(a), a petition filed under § 106.96(i)(3) of the interim final rule must contain all data and information relied upon by the manufacturer to demonstrate that the formula fulfills one or more of the quality factor requirements in § 106.96(i)(1) or (i)(2) of the interim final rule. Also, to help enhance the clarity and focus of these quality factor petitions, § 106.96(i)(4) of the interim final rule provides that each such petition shall address only a single infant formula formulation. Importantly, however, a single petition may address both § 106.96(i)(3)(i) and (i)(3)(ii) of the interim final rule for the same formulation.

Additionally, as noted previously in this document, the manufacturer of an infant formula, including an eligible infant formula, is responsible for ensuring that the formula meets the two quality factors established by the interim final rule. Regardless of whether the formula is a new infant formula or a "not new" formula, it is reasonable to expect the manufacturer to have scientific data and information demonstrating that the quality factors are met because only with such data and information can a manufacturer make an informed decision to market and lawfully distribute a particular formula. Given this responsibility and the means reasonably required to fulfill that responsibility, an infant formula manufacturer must necessarily establish and maintain records documenting that each eligible formula meets the two quality factors. As noted, the provisions of the interim final rule in § 106.96(i) recognize this need for records of the quality factor evidence for eligible infant formulas. Specifically, § 106.96(i)(5) of the interim final rule requires the manufacturer of each eligible infant formula to make and retain records to demonstrate that such formula supports normal physical growth in infants when fed as the sole source of nutrition and to demonstrate that the protein in such infant formula is of sufficient biological quality. The records established under § 106.96(i)(5) of the interim final rule must contain all relevant scientific data and information as well as a narrative explanation of why the data and information demonstrate that the formula meets the two quality factors established by the interim final rule. The requirement for a narrative explanation is a logical extension of the responsibility for ensuring that a formula meets the quality factors because without analyzing and summarizing the relevant data and information, a manufacturer has little or no basis to conclude that a particular formula supports normal physical growth or that it contains protein of sufficient biological quality. Additionally, this record requirement is reasonable, because without records, FDA has no way of determining whether a formula meets the quality factor requirements established under section 412(b)(1) of the FD&C Act. As noted in sections III and VIII.A, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act in order to effectuate an objective stated elsewhere in the FD&C Act. Thus, under sections 701(a) and 412(b)(1) of the FD&C Act, FDA has the authority to require a manufacturer of an eligible formula to maintain records demonstrating that their formula meets the quality factor requirements that apply to such formula. FDA emphasizes that this record-keeping provision for quality factor data and information required by § 106.96(i)(5) of the interim final rule applies to all eligible infant formulas that a manufacturer distributes or intends to distribute in interstate commerce and not simply to eligible formulas that are the subject of a petition under § 106.96(i)(3) of the interim final rule.

Although there are several distinct advantages to a manufacturer of an eligible infant formula that submits a petition to FDA under § 106.96(i)(3) of the interim final rule, the Agency recognizes that some manufacturers of eligible formulas may choose not to submit such a petition. Where no petition is submitted for an eligible infant formula, FDA intends to conduct an inspection of the formula's manufacturer and to review and evaluate the records for the formula that are required under § 106.96(i)(5) of the interim final rule. If the data and information or the narrative explanation in the records made and retained under § 106.96(i)(5) of the interim final rule do not demonstrate that the formula supports normal physical growth and that the protein in such infant formula is of sufficient biological quality, FDA will consider the formula to be adulterated under section 412(a)(2) of the FD&C Act and will pursue the Agency's customary regulatory process, which may include official communication with the firm such as a Warning Letter followed by appropriate legal remedies.

FDA received several comments related to the issue of currently marketed and previously marketed formulas. The Agency responds to these comments in this document.

(Comment 264) One comment stated that it did not believe that it is FDA's intent to require all infant formulas currently on the market in the United States to undergo the study required by proposed § 106.97(a) and if this is the Agency's intent, the comment strongly objects to this requirement as unnecessarily burdensome and without cause.

(Response) The commenter's statement of FDA's intent is not correct. As discussed previously in this document, all currently marketed formulas must be shown to meet the two quality factors established by the interim final rule. The Agency's intent was clear in that the 1996 proposed rule established quality factors for "infant formulas" and did not describe any subset that would not be covered by the requirements set forth in this interim final rule. Section 412(a)(2) of the FD&C Act states that infant formulas that do not meet the quality factor requirements are deemed adulterated. Significantly, this adulteration provision applies to all infant formulas (not just "new infant formulas"). Thus, all infant formulas must meet the quality factors established in this interim final rule. However, as discussed in detail previously in this document, the interim final rule includes in § 106.96(i) specific quality factor requirements for a formula that meets the definition of "eligible infant formula."

(Comment 265) One comment noted that not all infant formula products currently marketed in the United States have undergone a clinical study as described in proposed § 106.97(a). The comment asserted that there is no reason to believe these currently marketed products do not support normal physical growth and suggested that proposed § 106.97(a)(2)(i) be revised to reduce unnecessary clinical studies, particularly where currently marketed formulas that have not been the subject of a growth monitoring study have undergone small changes in formulation or processing. The comment stated that if proposed § 106.97(a)(2)(i) is not changed, it may pose an "unresolvable" dilemma in the case of future modifications of some currently marketed infant formulas.

(Response) The comment did not provide data or other information to explain the basis for its assertion that "there is no reason to believe these currently marketed products do not support "normal physical growth." FDA is a science-based Agency, and as such, must rely on valid data and other sound scientific information to draw conclusions about product safety, including the safety and nutritional sufficiency of infant formula.

FDA disagrees that the expectation that all currently marketed formulas be demonstrated with valid scientific evidence to satisfy the quality factor of normal physical growth will result in an "unresolvable" dilemma. The interim final rule provides specific provisions for manufacturers of eligible infant formulas to demonstrate that their products meet the quality factors of normal physical growth and sufficiency biological quality of the protein component, and § 106.96(i) of the interim final rule clearly contemplates that previously conducted growth studies, as well as other scientific data and information, may be used to demonstrate satisfaction of these quality factors. FDA believes that the opportunity to utilize existing data is certain to reduce the likelihood of requiring unnecessary growth monitoring studies.

Requirements to assure that quality factors have been met in the case of small changes to formulations is discussed under Comment 256 regarding submissions made under section 412(d)(3) of the FD&C Act.

(Comment 266) Another comment stated that the Agency has no way of being assured that an infant formula that may have been marketed at some time in the past, but which is not currently on the market, would meet quality factor requirements. Therefore, the comment asserts, if a manufacturer wanted to reintroduce such a formula into the market, the manufacturer would need to submit a new infant formula notification.

(Response) If a formula manufacturer wishes to reintroduce a formula into the market place, the reintroduced formula would need to meet the quality factors of normal physical growth and sufficient biological quality of the protein component. The mechanism in § 106.96(i) of the interim final rule contemplates this situation and establishes quality factor requirements for eligible infant formulas, which include certain previously marketed formulas. In addition, under § 106.96(i)(5) of the interim final rule, the manufacturer of an eligible infant formula, including a previously marketed formula that is reintroduced, is required to make and retain records that demonstrate that such formula meets the two quality factors. FDA disagrees, however, that a reintroduced formula must necessarily be the subject of a new infant formula submission because the requirement to make such a submission applies only to a formula that is a "new infant formula" as defined by section 412(c) of the FD&C Act and § 106.3 of the interim final rule. If a previously marketed formula is altered such that the formula would be classified as a "new infant formula," such formula would need to be the subject of a new infant formula submission, and would not be eligible to meet the quality factors under § 106.96(i) of the interim final rule.

(Comment 267) One comment requested that FDA confirm that the protein quality factor pertains only to new situations that arise after the effective date of the quality factor requirements. The comment argued that this is reasonable because the assurance of quality factors of all currently marketed formulas has been provided by the good health of infants that have been raised on those formulas over the years.

(Response) Under section 412(b)(1) of the FD&C Act, quality factor requirements apply to all infant formulas; not only new infant formulas. As such, currently marketed formulas must meet the quality factors under this interim final rule, including the quality factor of sufficient biological quality of protein. However, as is explained previously in this document, currently marketed formulas that are "eligible formulas" under § 106.96(i) of the interim final rule have some flexibility in terms of how satisfaction of the two quality factors may be demonstrated.

I. Records Demonstrating Compliance With the Quality Factor Requirements for Infant Formulas That Are Not Eligible Infant Formulas

For consistency with other records requirements, FDA is adding a provision in the interim final rule (§ 106.96(d)) that requires a manufacturer of a new infant formula that is not an eligible infant formula to make and retain certain records demonstrating that such formula meets the quality factor of normal physical growth. Likewise, FDA is adding a provision in the interim final rule (§ 106.96(h)) that requires a manufacturer of a new infant formula that is not an eligible infant formula to make and retain certain records demonstrating that the formula meets the quality factor of sufficient biological quality of protein. As noted previously in this document in section VIII.A, it is reasonable and necessary for the efficient enforcement of the FD&C Act for FDA to require a manufacturer of infant formula to make and retain records demonstrating that the formula satisfies the quality factors requirements. These records may assist FDA in determining whether an infant formula meets the quality factor requirements.

As is discussed further in section IX.F, in order to comply with this records requirement, a manufacturer of a new formula that is not an eligible infant formula will be required to make and retain records demonstrating compliance with the growth monitoring study requirements under § 106.96(b) of the interim final rule, or make and

retain records demonstrating satisfaction of an applicable exemption under section § 106.96(c) of the interim final rule.

In the proposed rule, proposed § 106.97(a)(i)(B) would have required a manufacturer to collect and maintain, in the growth study, anthropometric measures of physical growth. This interim final rule expands and clarifies this collection and maintenance requirement, to require that a manufacturer make and retain records demonstrating compliance with the growth monitoring study requirements under § 106.96(b) of the interim final rule, or in the alternative, records demonstrating satisfaction of an applicable exemption under section § 106.96(c) of the interim final rule.

Likewise, the interim final rule includes a provision (§ 106.96(h)) that requires a manufacturer of a new infant formula to make and retain certain records demonstrating that the formula meets the quality factor of sufficient biological quality of protein. With respect to the quality factor of sufficient biological quality of protein, the proposed rule would have required a manufacturer of an infant formula to collect and maintain data establishing that the biological quality of protein in the infant formulas is sufficient to meet the protein requirements of infants proposed § 106.97(b)(1) . As is discussed in further detail in section IX.F, this interim final rule clarifies that the requirement to make and retain records demonstrating that the formula has sufficient biological quality of protein includes, when applicable, records demonstrating satisfaction of an applicable exemption under § 106.96(g) of the interim final rule. If the formula manufacturer is not seeking an exemption from the requirements of § 106.96(f) of the interim final rule, the formula manufacturer would need to make and retain records demonstrating compliance with the requirements under § 106.96(f) of the interim final rule.

J. Establishment of Other Quality Factors

1. General Comments

Several comments agreed with FDA's tentative conclusion in the 2003 reopening notice that the quality factors of normal physical growth and protein biological quality are sufficient at this time for assessing the bioavailability of nutrients in an infant formula and that the physical growth and protein quality would be considered reasonable benchmarks, presuming the infant formula contains all nutrients required by section 412 of the FD&C Act. Other comments recommended that the Agency identify additional quality factors and establish requirements for such factors.

(Comment 268) One comment expressed concern about the Agency's suggestion in the 1996 proposal (61 FR 36154 at 36181) that additional quality factors may be identified on a case-by-case basis for specific formula products, stating that this would create difficulties for manufacturers without more explicit guidance as to what is required.

(Response) FDA is not including in the interim final rule requirements for quality factors other than those for normal physical growth and biological quality of the protein. The Agency notes that, in the future, it may propose requirements for additional quality factors for infant formula, or nutrients in such formula, in general or for specific types of formula or for specific nutrients. However, any additional quality factors requirements will be established in a future rulemaking or FDA will make recommendations in a future guidance established under FDA's GGPs (21 CFR 10.115). Both of these processes would include prior notice and the opportunity for public participation.

(Comment 269) One comment stated that, due to the increasing complexity of infant formula ingredients, benchmarks such as growth and protein quality do not evaluate the effect of new ingredients, such as long-chain polyunsaturated fatty acids and probiotic microorganisms or other complex ingredients. The comment suggested that instead, FDA evaluate overall nutrient quality and availability, targeted vitamins, minerals, and macronutrients.

(Response) The quality factors of normal physical growth and sufficient biological protein quality are necessary to demonstrate that the required nutritional components of infant formula are bioavailable, in order to help ensure that the formula supports healthy growth. Evaluation of normal physical growth by a well-controlled growth monitoring study and evaluation of the biological quality of the protein by PER rat bioassay are not intended to, and do not, evaluate other purported effects of new ingredients (e.g., effects of long-chain polyunsaturated fatty acids on visual development or effects of probiotic microorganisms on gut flora). Thus, the suggestion of this comment is beyond the scope of this interim final rule.

2. Quality Factors for Fat, Calcium, and Phosphorus

In the 1996 proposal (61 FR 36154 at 36182), FDA stated "because of the potential seriousness of the public health impact of not meeting quality factors, FDA also believes that it is desirable to establish additional quality factors, as soon as they are warranted by evolving scientific knowledge, to ensure adequate nutrient bioavailability." The Agency notes that the CON/AAP Task Force (Ref. 67) recommended metabolic balance studies to determine whether a formula meets quality factors for fat, calcium, and phosphorus. FDA specifically requested comment on whether the scientific evidence and usefulness of results are sufficient to support establishing quality factor requirements for nutrients other than protein, such as fat, calcium, and phosphorus, and if so, what assurances should be established for such factors (61 FR 36154 at 36181). The Agency also requested comment on balance studies or other methods that could be used to assess potential quality factor requirements for these three nutrients. This opportunity was renewed with the 2003 reopening of the comment period.

Several comments responded to FDA's request for comment on whether quality factor requirements should be established for fat, calcium, and phosphorus.

(Comment 270) One comment supported including quality factor requirements for fat, calcium, and phosphorus in assessments of the nutritional adequacy of formulas, and stated that manufacturers are currently expected to include these measures in the clinical evaluation of their formulas and the measurement of these quality factors should not present difficulties to manufacturers or those involved in the clinical study of infant formulas.

(Response) FDA disagrees with this comment to the extent that it asserts that manufacturers currently measure the bioavailability of fat, calcium, and phosphorus in their clinical evaluations of infant formulas. To date, FDA has not recommended that manufacturers include metabolic balance studies to evaluate the adequacy of fat, calcium, and phosphorus in new infant formulas. In fact, in the 1996 proposal, FDA tentatively concluded that the clinical and nutritional sciences had not reached a level of development such that specific tests were available to establish that infant formulas could be demonstrated to satisfy quality factors for each of the essential nutrients listed in § 107.100, except for protein. In particular, the Agency expressed

concern about the absence of meaningful measures for the assessment of the bioavailability of calcium and phosphorus. At the same time, FDA noted that studies of infant excretion of fat indicate that the fats in formula are highly digestible, thus mitigating questions about fat bioavailability. The comment did not provide any information to contradict the Agency's tentative conclusion that quality factor requirements should not be established for nutrients other than protein. Accordingly, FDA declines to establish quality factor requirements for fat, calcium, and phosphorus in this interim final rule.

(Comment 271) Some comments disagreed with FDA's statement in the 1996 proposal (61 FR 36154 at 36187) about the degree of technical difficulty in performing fat balance studies, saying that metabolic studies are difficult to perform well and are conducted at few research centers (Ref. 67).

(Response) FDA agrees in part with this comment. In the 1996 proposed rule, FDA stated that the current method for measuring fat excretion is noninvasive, by which FDA meant that these studies consisted of collecting feces and urine which are naturally excreted from the body of infants. However, as noted in the comment, the accurate collection of such specimens is technically very difficult and, in some or all cases, would require hospitalization to ensure accurate sampling and measurement. The limitations on such studies are a second separate reason not to require metabolic balance studies of infant formula.

(Comment 272) With respect to fat balance studies, one comment stated that the level of fat malabsorption that leads to clinical or body composition effects is not well defined and may not be 15 percent as stated in the 1996 proposal (61 FR 36154 at 36181). The comment concluded that this factor adds to the limitations of fat balance studies.

(Response) FDA agrees with this comment that the level of fat malabsorption that leads to clinical or body composition effects is not well defined and that this fact would be a further limitation to fat balance studies. The mean amount of fat not absorbed is approximately 15%, but the degree of malabsorption depends on the type of fat at issue. One source shows that the range of fat excreted (Ref. 83, pp.164–165) is between 0.66 to 9.3 percent of intake when vegetable oils are the fat source in a milk-based infant formula, and that infants excrete a higher proportion of fat when homogenized cow milk is consumed; the latter level is related to the type of fat in cow milk (butterfat), which young infants cannot readily digest because they lack the necessary bile salts and enzyme. Thus, this comment supports the Agency's decision not to establish quality factor requirements for fat.

(Comment 273) One comment opposed the establishment of quality factor requirements for fat, calcium, and phosphorus because, the comment asserted, the collection of formula intake and stool data by untrained parents (which would be part of a metabolic balance study) would result in extremely inaccurate data if studies were conducted on term infants in the home.

(Response) FDA agrees that the use of untrained parents to collect study data is one very practical limitation of a balance study and thus, is an additional reason to not identify, and establish requirements for, quality factors for fat, calcium, and phosphorus at this time.

(Comment 274) Other comments noted that financial and, perhaps, ethical difficulties may be associated with balance studies because such studies may require hospitalization and restraint of infants. The comment characterized hospitalization as "invasive."

(Response) FDA does not agree with the comment that hospitalization is conventionally considered "invasive." However, the Agency agrees that to ensure maximum accuracy in the collection of infant input and output information in a balance study, it could be necessary to confine the infant study subjects to a hospital and, in some cases, to restrain the subjects. FDA agrees that these two possibilities are significant negatives of establishing a quality factor for fat and requiring a balance study of a new formulation of an infant formula to demonstrate that the quality factor is satisfied.

(Comment 275) Several comments suggested that fat, calcium, and phosphorus balance studies should be performed on a voluntary basis when the manufacturer believes they are necessary to assess specific effects of a formula or ingredient.

(Response) FDA does not disagree with this comment. To the extent that a formula manufacturer believes that fat, calcium, or phosphorus studies would be meaningful for evaluating a particular infant formula, FDA would generally not object to the conduct of such a study. Importantly, however, prior to conducting any such study, the manufacturer should be certain that data from such study are necessary and will be meaningful so as to avoid subjecting the infants study subjects to unnecessary testing.

(Comment 276) One comment stated that balance studies are more useful for comparing formulas than for assessing adequacy of a particular formula and suggested that the decision to include balance studies should be made during development of a study protocol.

(Response) FDA agrees with this comment to the extent that it asserts that a balance study must be designed to answer the research question at issue. However, the comment did not explain how adequacy of a particular formula could be determined without comparing the test formula to a control formula that has already been evaluated for nutritional adequacy.

Generally speaking, a balance study would be used to compare one factor under investigation (e.g., the fat blend of a formula) while all other factors are kept constant. Thus, in a study comparing the fat blend of one formula to another, the study design would require that the test and control formulas contain all the same nutrients except the fat source, which would be different in the test and control formulas (Refs. 83 and 84). As noted, however, FDA is affirming the Agency's tentative 1996 decision that no metabolic balance studies will be required of new formulations of infant formulas.

Several comments addressed specific aspects of balance study design and methodology.

(Comment 277) One comment pointed out the desirability of using comparable levels of minerals in both the test and control formulas since mineral retention in balance studies tends to become more positive with higher intakes.

(Response) FDA agrees that mineral retention in balance studies tends to become more positive with higher intakes and that, when conducting a balance study, it is desirable to use comparable levels of minerals in test and control formulas to reduce the potential for confounding, which could result in misinterpretation of study results. As noted, however, FDA is affirming the Agency's tentative 1996 decision that no balance studies will be required of new formulations of infant formulas.

(Comment 278) One comment asserted that serum alkaline phosphatase determination would be of no value in calcium and phosphorus balance studies as the time course of its response is slower than the brief period of a balance study and there are age specific, gestational, and nutrient effects that complicate its interpretation.

(Response) FDA agrees with this comment that alkaline phosphatase

analysis in balance studies would be of limited value for the reasons given. As noted, however, FDA is affirming the Agency's tentative 1996 decision that no balance studies will be required of new formulations of infant formulas. Therefore, this comment has no bearing on the interim final rule.

(Comment 279) Another comment pointed out that preterm infants, who have sometimes been used as subjects for balance studies, would not be appropriate subjects for the studies of formulas for term infants.

(Response) FDA agrees with this comment. Preterm infants would not be appropriate participants for balance studies evaluating the bioavailability of infant formulas intended for term infants because each group has specific nutrient needs that are not identical. In particular, preterm infants are at great risk for malnutrition and require relatively greater amounts of energy, protein, calcium, phosphorus, vitamin D, and vitamin A levels compared to the needs of healthy term infants. Thus, extrapolation of data from preterm infants to healthy term infants could result in erroneous conclusions about necessary nutrients for healthy term infants. For a study of a formula intended for use in term infants, the study population must be composed of such infants. Because the Agency has confirmed its 1996 tentative decision not to require balance studies of infant formula, however, no change in the interim final rule is required in response to this comment.

(Comment 280) One comment indicated that sensitivity of balance studies is greater with a crossover design (Ref. 67). Another comment pointed out that crossover design would subject an infant to a longer period of confinement and restraint and considered this unwarranted for routine testing of all products.

(Response) FDA agrees that a crossover design could be used in a balance study to increase the power of a study using a small study population because each participant would serve as his or her own control. Importantly, however, balance studies require that the infant be confined to a hospital for 72 hours for each study period, immobilized in a "papoose-like" devise that permits all urine and feces to be continuously collected. Given these necessary conditions of a balance study, this type of study should only be performed when absolutely necessary because of its extremely restrictive nature (Ref. 85). Given the lack of sound methods for measuring essential nutrients and the lack of predictive outcomes from many of these of studies, FDA has determined that balance studies should not be required by this interim final rule for any nutrient in infant formula.

Several comments addressed the use of methods other than balance studies to evaluate bioavailability of total fat, calcium, and phosphorus.

(Comment 281) One comment concurred with FDA's tentative conclusion in the 1996 proposal that there is no current practical and generally accepted alternative to balance studies for assessing bioavailability of these nutrients (61 FR 36154 at 36188). However, the comment noted that newer measures of assessing bone mineralization directly hold considerable promise for evaluating these nutrients in infant formulas, suggesting that these methods could be useful when they become more standardized and more normative data become available for infants.

(Response) FDA agrees with this comment that, at the time of the 1996 proposal, new means of assessing bone mineralization directly, such as dual-energy x-ray absorptiometry (DEXA) scans, appeared promising. However, DEXA has not achieved sufficient reliability to be considered a "gold standard" for body composition of infants and is currently confined largely to use as a research tool. The Agency has considered the data presented at the 2002 meeting of the FAC, as well as recent studies (Refs. 86 and 87), and finds no basis to require DEXA scans in growth monitoring studies. Accordingly, the Agency is not persuaded at this time to add tests using these methods as a requirement to demonstrate the bioavailability of an infant formula or of calcium and phosphorus in infant formulas.

(Comment 282) One comment stated that, when alterations in fat source or composition are proposed, the manufacturer should be required to demonstrate that study subjects' serum fatty acid levels are comparable to those of breast-fed infants or infants fed other standard infant formulas.

(Response) FDA does not agree with this comment. The comment provided no evidence or reasoning to support the recommendation that the evaluation of serum fatty acid levels of infants consuming a new infant formula formulation should be required to be measured and determined to be equivalent to infants that are breast-fed or are consuming a standard infant formula. Moreover, FDA is aware of no scientific evidence that suggests that measurement of serum fatty acids would be a means to assessing the ability of an infant formula to ensure healthy growth. Although measuring serum fatty acids reflects, to some extent, an infant's diet, serum fatty acids are also influenced by other factors such as timing of the blood draw in relation to formula consumption and hormonal responses. Finally, the fatty acids in circulation do not predict growth. The levels of some fatty acids can be used to determine whether there are adequate levels of essential fatty acids (linoleic and linolenic) but these circulating levels are not directly related to normal physical growth.

For the reasons discussed previously in this document, the Agency is not establishing in this interim final rule requirements for quality factors related to fat, calcium, or phosphorus.

3. Quality Factor for Iron

In the 1996 proposal (61 FR 36154 at 36182 and 36189), FDA requested comment on whether a quality factor for iron should be established and what data would be needed to establish that the iron in an infant formula is sufficiently bioavailable and maintains the iron status of infants that consume the formula. The Agency observed that the data on iron bioavailability would need to demonstrate that an infant formula provides enough iron to prevent iron deficiency and anemia. The Agency expressed concern, however, that a growth monitoring study of full-term infants aged zero to four to five months might not be sensitive enough to detect significant differences in iron bioavailability of a formula product because healthy, full-term infants are usually born with adequate iron stores to maintain normal iron status for the first three to four months of life—the time when the growth monitoring study would be conducted. Without assurance that the test results would be meaningful, the Agency tentatively decided not to establish quality factor requirements for iron.

A number of comments supported the inclusion of a quality factor for iron for infant formulas and supported establishing requirements for such quality factor. Other comments objected to a general quality factor for iron.

(Comment 283) One comment stated that manufacturers are currently expected to include these measures in the clinical evaluation of their formulas and thus, it is not anticipated that measurements of this quality factor should present difficulties to manufacturers or those involved in the clinical study of infant formulas.

(Response) FDA disagrees with this comment to the extent that it asserts that manufacturers currently measure the bioavailability of iron in their clinical

evaluations of infant formulas. To date, FDA has not recommended that manufacturers include metabolic balance studies to evaluate the adequacy of iron in new infant formulas. In fact, in the 1996 proposal, FDA tentatively concluded that the clinical and nutritional sciences had not reached a level of development such that specific tests were available to establish that infant formulas could be demonstrated to satisfy quality factors for each of the essential nutrients listed in § 107.100, except for protein (61 FR 36154 at 36182). This comment did not provide any information to contradict the Agency's tentative conclusion that quality factor requirements should not be established for nutrients other than protein. Accordingly, FDA declines to establish a quality factor for iron in this interim final rule.

(Comment 284) Another comment regarded the failure to include a quality standard for iron as a problem, noting that iron deficiency would not be detected by anthropometric (weight) measurements used to evaluate the normal physical growth quality factor.

(Response) FDA disagrees in part with this comment. The Agency agrees that iron insufficiency will not be readily detected in a growth study evaluating normal physical growth. Importantly, however, as noted in the preamble to the proposed rule, infants are born with iron stores sufficient until age three to four months. For this reason, the growth monitoring study required by § 106.96(b) of the interim final rule to assess normal physical growth will be neither sensitive enough nor long enough to show iron deficiency. Thus, FDA is not adding a requirement to measure iron to the requirements for the growth monitoring study.

(Comment 285) Another comment strongly supported establishing a quality factor for iron, concluding that implementation of the iron status quality factor would go a long way toward providing the scientific data to resolve the issue of what level of iron is correct for infant formula.

(Response) FDA agrees that iron status is important to infants' nutritional well-being. Although there are some available methods for evaluating iron status, the most sensitive of these methods require invasive procedures. Balance studies also offer a means to assess bioavailability of iron but the balance method is less sensitive and, as noted previously in this document, requires hospitalization and prolonged restraint of the infants.

As noted in the 1996 proposed rule, term infants are generally born with adequate iron stores to meet their needs for the first few months of life. Even if suitably sensitive and noninvasive methods were available to measure iron status in infants, it is questionable whether such measurements made during early infancy would provide meaningful information on the bioavailability of iron in infant formulas. For these reasons, FDA does not agree that the Agency should establish a quality factor for iron at this time.

The purpose of establishing a quality factor for a nutrient is to require a determination of whether the nutrient is bioavailable in the infant formula, i.e., that the nutrient is digested and absorbed by the infant as the product is formulated for market. The question of what level of a nutrient is "correct" for infant formula is better addressed by studies with outcome measures designed to answer that question specifically.

(Comment 286) One comment stated that a poorly available source of iron would be a problem for an infant between the ages 4 and 12 months fed only formula and noted that, while feeding only formula to healthy infants from 4 to 12 months of age is not consistent with CON/AAP recommendations, there are instances where a formula-only diet has been fed for extended periods of time to infants 4 to 12 months of age.

(Response) FDA agrees that there may be rare cases in which formula is the exclusive nourishment provided to infants after age 4 months and that it could be problematic if that formula is deficient in iron. Importantly, however, the comment included no evidence to establish the concern that currently marketed formulas are poor sources of iron. Infants are usually seen by their pediatricians every 1 to 2 months during the first year of life, and, consistent with AAP recommendations, most but not all infants are starting complementary foods by 4 months of age (Refs. 70 and 88). Thus, these rare instances of formula-only diets in older infants do not require the Agency to establish a quality factor for iron, particularly given the factors weighing against such establishment.

(Comment 287) One comment recommended that studies of iron status in infants be performed only when the manufacturer believes that such studies may help assess effects of a specific formula or ingredient.

(Response) FDA does not disagree with this comment. To the extent that a formula manufacturer believes that an iron status study would be meaningful for evaluating a particular infant formula with a specific ingredient, FDA would not object to the conduct of such a study. Importantly, however, before conducting any such study, the manufacturer should be certain that data from such study are necessary and will be meaningful so as to avoid subjecting the infant study subjects to unnecessary testing.

(Comment 288) Several comments noted that the quality factor for iron would be of little value in the first four months of life, when the standard growth study would be conducted.

(Response) FDA agrees with this comment. As noted in the 1996 proposed rule, full-term infants are generally born with adequate iron stores to meet their iron needs for the first few months of life, a fact that restricts the ability to conduct an accurate assessment of iron bioavailability during the period of the growth monitoring study. The Agency did not receive data or other information challenging FDA's statement about newborn iron stores nor did any comment dispute that these stores would interfere with the ability to measure iron bioavailability during the growth monitoring study.

(Comment 289) Other comments objected to establishment of a quality factor for iron status because it would require an invasive procedure of drawing blood. The comments further stated that when blood draws are required in infants, physicians are more reluctant to conduct studies on well babies and parents are much more likely to refuse enrollment or drop out of the study.

(Response) FDA agrees that establishing a quality factor for iron and a requirement to show that this quality factor is satisfied by an infant formula would likely require blood draws of study subjects, which would be an invasive procedure not otherwise required in the growth monitoring study. However, as noted previously in this document, FDA is not establishing a quality factor for iron because it is not possible to perform an accurate assessment of iron's bioavailability in the early months of infancy, the period during which formula is consumed as the sole source of nutrition. FDA concludes that the risk, however small, of the invasive procedure of a blood draw is not justified given that any resulting iron bioavailability data would be of very limited, if any, value.

(Comment 290) One comment noted that the creation of a quality factor for iron is complicated by the presence in the U.S. market of formulas with varying levels of iron fortification, some of which are nutritionally adequate from the standpoint of iron and others which may not be adequate, but still meet the

standards of the FD&C Act. The comment contended that it makes little sense to develop a quality factor for a nutrient that is not required by law in formulas for healthy infants in nutritionally adequate amounts and that no quality factor recommendation would be appropriate until and unless the FD&C Act is modified to establish a required level of bioavailable iron.

(Response) FDA disagrees with this comment. Although the comment is correct that § 107.100 permits a wide range of iron content in infant formula (0.15 to 3 mg/100 kcal), the comment appears to confuse the range of permitted iron levels in infant formulas with the need for the iron in formulas to be bioavailable. The iron in infant formula must be bioavailable, regardless of the amount present. As noted, FDA is not establishing a quality factor for iron in this interim final rule, but not for the reason given in this comment.

(Comment 291) One comment recommended that FDA establish a quality factor for iron and require animal assays to assess the iron's bioavailability, rather than require additional assessment measures in a standard growth study.

(Response) As explained previously in this document, FDA is not establishing a quality factor for iron because of constraints on the use of available methods for measuring the iron status of healthy term human infants. The comment did not identify any animal assay that could potentially be used to demonstrate that a particular infant formula satisfies an established quality factor for iron. The Agency is aware that nonhuman primate and rodent models have been used in studies of iron status and infant neurocognitive and neurobehavioral development (Ref. 89), and newborn piglets have also been used in studies of nutrient absorption from infant formulas, but the comment provided no animal data on iron bioavailability that could readily be applied to infants. Without such information, FDA is not persuaded to establish a quality factor for iron and to require an animal test to demonstrate the bioavailability of iron in infant formula.

(Comment 292) Several comments that supported inclusion of a quality factor for iron concluded that serum ferritin (i.e., a stage 1 measurement of iron status) would be the appropriate quality factor measurement because if ferritin is sufficient in the infant, there is no risk that stage 2 or 3 iron status will be reached. The comment further suggested that a measurement of ferritin alone would make studies more efficient, cost effective, and less invasive.

(Response) FDA agrees that serum ferritin is a very useful tool for assessing iron nutritional status. However, as FDA noted in the proposed rule (61 FR 36154 at 36182), healthy, full-term infants are usually born with adequate iron stores to maintain normal iron status for the first 3 to 4 months of life—the period of time that a growth monitoring study will be conducted. Moreover, the serum ferritin assessment requires an invasive procedure (blood draw). For these reasons, FDA declines to establish the measurement of ferritin as a quality factor requirement for new infant formulas.

For the foregoing reasons, FDA is not revising § 106.96 in this interim final rule to establish a quality factor for iron.

4. Standard Laboratory Measures

In the 1996 proposal, FDA requested, and received, comment on whether the collection of standard laboratory measures, such as complete blood count (white blood cell count and red blood cell count), hemoglobin concentration or hematocrit percentage, and serum or plasma concentrations of albumin, urea, nitrogen, electrolytes (sodium, potassium, and chloride), alkaline phosphatase, and creatinine, would be useful and necessary information for determining whether a formula causes adverse consequences that may not be reflected in the quality factor requirements for normal physical growth (61 FR 36154 at 36184).

(Comment 293) One comment pointed out that FDA did not propose to make serum chemistries into quality factors and that there are situations where the relevant clinical endpoints would be biochemical indicators of nutritional status.

(Response) FDA notes that the comment did not submit any data or other information identifying the particular situations that would require serum chemistries to evaluate the nutritional adequacy of an infant formula or why serum chemistry evaluations should be a standard requirement for growth monitoring studies. The growth monitoring study, which is often conducted on an outpatient basis, evaluates the adequacy of the formula to support normal physical growth and an infant's tolerance of the formula. Although the AAP report (Ref. 67) recommended that some blood tests might be useful at the conclusion of the study period, the decision lies with those responsible for designing and conducting the study. FDA concludes, as discussed in the 1996 proposed rule, that it is not appropriate to require invasive procedures, such as blood draws, as part of this interim final rule. As discussed in this document, the Agency encourages manufacturers to evaluate each new formulation to determine whether the nature of the particular new formulation suggests that serum blood chemistries should be required. Accordingly, FDA is making no change in the interim final rule in response to this comment.

(Comment 294) One comment stated that doing such blood work is not a standard practice of investigators and that drawing blood would violate the principles that the FDA cites for protecting the infant from unnecessary testing. The comment further asserted that establishing a requirement for drawing blood would cause many parents to refuse to have their infants participate in a study. Thus, the comment argued, collecting this information routinely would not be useful and could be detrimental for the timely completion of clinical studies.

(Response) FDA agrees with this comment. No comments submitted in response to the Agency's request included data or other information to demonstrate that standard blood chemistry measures are necessary to evaluate whether an infant formula supports normal physical growth of infants, and without question, collecting such data would require blood draws, which is an invasive procedure. Accordingly, FDA is not persuaded to require these standard laboratory measures as a part of all growth studies.

FDA notes, however, that some or all of these measures may be appropriate for the testing of certain formulas or for certain changes in a particular formula. For example, if a formula is developed with an unusual renal solute load, measures of albumin, urea, electrolytes, and creatinine in serum may be appropriate. The Agency encourages manufacturers to evaluate each new formulation to determine whether testing a particular formulation requires some or all of these blood chemistries.

For these reasons, FDA is making no change in the interim final rule in response to these comments.

K. Miscellaneous Comments on Quality Factors

(Comment 295) One comment challenged the statement in the 1996 proposal (61 FR 36154 at 36179) that referred to selenium as a "nonrequired nutrient." The comment asserted that selenium is an essential nutrient for infants, i.e., a required nutrient for infants.

(Response) FDA is aware that selenium is an essential nutrient for infants. In the preamble to the 1996 proposal (61 FR 36154 at 36155), FDA stated "For the purpose of this document, the nutrients that are required to be in infant formula under § 107.100 will be referred to as "required nutrients." Thus, the term "nonrequired" referred to the status of selenium on the Congressionally-mandated list of ingredients set out in section 412(i) of the FD&C Act and established by regulation at 21 CFR 107.100. The list of minimum and maximum specifications for nutrients in infant formulas was most recently revised in 1986, 3 years before establishment of a recommended dietary allowance for selenium for infants (Ref. 60).

Additionally, in the Federal Register of April 16, 2013 (78 FR 22442), FDA published a proposed rule to amend the regulations on nutrient specifications and labeling for infant formula to add selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

(Comment 296) One comment agreed with FDA's proposal (61 FR 36154 at 36178) to revoke the requirement in current § 106.30(c)(2) for determination of vitamin D by a rat bioassay method.

(Response) In this interim final rule, FDA is revoking the requirements in current § 106.30(c)(2) for the determination of vitamin D by a rat bioassay method. As explained in the proposed rule, this rat bioassay for vitamin D is no longer a reasonable requirement because appropriate animals for conducting this test are difficult to acquire (Ref. 90), and an alternate analytical method for the determination of vitamin D in infant formulas has been approved by AOAC (Ref. 91).

IX. Subpart F—Records and Reports

As noted in the introductory section of this preamble, in 1991, FDA revised subpart C in part 106, and established records and reports requirements for infant formula (56 FR 66566, December 24, 1991). These regulations were authorized by section 412 of the FD&C Act, as amended by the 1986 amendments, and replaced the original records regulations established in 1982 (47 FR 17016, April 20, 1982).

Thereafter, in 1996, the Agency proposed additional revisions to the infant formula records and reports regulations and proposed to redesignate these requirements as subpart F in part 106. The proposed requirements related to batch (production aggregate) records (proposed § 106.100(e)), records to document compliance with CGMP (proposed § 106.100(f)), infant formula distribution records (proposed § 106.100(g)), and records of regularly scheduled audits (proposed § 106.100(j)). As noted in the proposed rule, FDA is retaining 21 CFR 106.100(l) of the current infant formula regulations. Thus, all of the records that are required to be maintained under this interim final rule shall be made readily available for FDA inspection.

FDA received a number of comments on the proposed revisions to the records and reports requirements. These comments are summarized in this document along with the Agency's responses.

A. General Comments on Records (Proposed § 106.100)

(Comment 297) One comment objected to the phrase that relevant records shall "include but are not limited to" in proposed § 106.100(e), (e)(1), (e)(3), (f), (f)(6), and (g). The comment asserted that the required records should be limited to focus on and incorporate the statutory reference to "necessary" documents, rather than the broader language that was proposed.

(Response) FDA is removing the phrase "but are not limited to" language from the proposed sections identified in the comment, but not for the reason stated in the comment. The language is unnecessary because the words "include," "includes," and "including" have the connotation that the itemized list that follows is not exclusive.

Importantly, however, the Agency did not intend to identify in the proposed codified each and every record that may be required where these terms appear. Section 412(b)(4)(A)(i) of the FD&C Act requires the Secretary to establish requirements that provide for the retention of all records "necessary to demonstrate compliance with the good manufacturing practices and quality control procedures. . . ." Proposed § 106.100(e), for example, would require a manufacturer to prepare and maintain records that include "complete information relating to the production and control of the batch." Although proposed § 106.100(e) specifies certain records that must be established and maintained under this section, this provision does not list every record related to "complete information relating to the production and control of the batch." Thus, if a manufacturer includes in its master manufacturing order certain documents that are related to the production and control of a production aggregate of infant formula, such information would be required to be maintained under this regulation even if the documents are not expressly identified in proposed § 106.100(e)(1).

(Comment 298) One comment asserted that the proposed documentation requirements are very burdensome and would necessitate additional staffing to implement. However, the comment claimed that it was difficult to quantify the additional cost without further clarification and that it was not possible to comment further on the estimated annual recordkeeping burden until the regulations are finalized.

(Response) This comment simply asserts that records requirements are burdensome without any attempt to quantify recordkeeping costs or to estimate the recordkeeping burden. Also, the comment included no supporting data or information for FDA to consider and to which the Agency could respond. Therefore, FDA is not revising the interim final rule in response to this comment.

(Comment 299) Another comment observed that in the proposed rule, FDA proposes large increases in recordkeeping, which will involve recording results for each batch (production aggregate) of ingredients, including the source of production, the batch (production aggregate) number, the lot (production unit) number, and analysis records of raw materials.

(Response) The records required by this interim final rule are necessary to achieve the public health goals of the FD&C Act, including the CGMP regulations, which are designed to prevent the adulteration of infant formula caused by equipment or utensils, automatic equipment, ingredients, containers, and closures, as well as to prevent adulteration of formula during manufacturing, packaging, and labeling. The comment does not challenge these goals or contradict the need for these records. Accordingly, FDA is not revising the interim final rule in response to this comment.

(Comment 300) One comment claimed that under the proposed rule, production records such as pH, temperature, solids, fat, protein, and lactose would also have to be retained for 2 years after the expiration date of the product and that this will be very expensive and contribute little to the overall quality of the product. The comment also questioned the need to retain results for 2 years following a product's withdrawal from marketing.

(Response) It is unclear which provision of the proposal is the subject of this comment. The proposed rule did not contain, and the interim final rule

does not contain, a 2-year record retention requirement.

The comment may be referring to current 21 CFR 106.100(n), which requires retention of production records for 1 year after the expiration of the shelf-life of a infant formula or 3 years from the date of its manufacture, whichever is greater. FDA did not propose any changes to this requirement, and is making no changes to this requirement in this interim final rule. Although the comment asserted that required records retention would be "very expensive," the comment did not offer any data or information to quantify any added expense. Similarly, although the comment asserts that records retention will contribute little to the overall quality of infant formula, the comment provided no data, information, or explanation to support its assertion about the alleged lack of effect on product quality. Accordingly, FDA is making no revisions to the interim final rule in response to this comment.

B. Production Aggregate Production and Control Records (Proposed § 106.100(e))

As discussed in section IV.C, to improve the clarity of the interim final rule and eliminate certain ambiguity and confusion, FDA is establishing in this interim final rule new terminology to refer to the basic volumes of formula produced by a manufacturer. The two new terms, which are identified in § 106.3 of the interim final rule, are "production aggregate" and "production unit." In the discussion that follows, FDA is adding the parenthetical "(production aggregate)" or "(production unit)," as appropriate, after the word "batch" or "lot" when used in a comment summary and is substituting the new term "production aggregate" or "production unit" for "batch" or "lot," as appropriate, in responses to comments and where "batch" or "lot" was used in the proposed rule.

(Comment 301) One comment acknowledged that complete documentation of the manufacture and release of each batch (production aggregate) of infant formula (which proposed § 106.100(e) would require) is essential, and such documentation must be readily available for review. However, the comment argued that compilation of such documentation into one record for each batch (production aggregate) would be redundant and overly burdensome to manufacturers having established documentation review systems designed to provide retrieval of all critical information upon request. The comment requested that the Agency clarify whether current practices could be continued under this regulation.

(Response) FDA is not able to respond directly to the request for clarification concerning the continuation of current practices because there are multiple infant formula manufacturers in the U.S. and the practices of those manufacturers are both likely to be different and are likely to have changed since the submission of the comment.

Importantly, however, the Agency agrees with the comment that establishing and maintaining complete documentation of a production aggregate of infant formula is essential because the manufacturer, FDA, or both may need to access and consult the records rapidly in order to identify and resolve a problem related to the production of a particular production aggregate before the infant formula product is released for distribution. In establishing § 106.100(e) of the interim final rule, FDA's goal is to ensure that the complete production aggregate documentation is immediately available and accessible to both FDA and the manufacturer. In the case of records maintained as hard copies, immediate availability and accessibility is accomplished by co-locating all required records relating to a particular production aggregate (i.e., by establishing a single, consolidated record in one physical location). For records that are maintained electronically, immediate availability and accessibility is accomplished by linking electronically all required records that pertain to the same production aggregate in a way that will permit their instantaneous retrieval.

The Agency disagrees that maintaining a single record for each production aggregate would be overly burdensome to manufacturers who have established documentation review systems that can retrieve all critical information immediately upon the Agency's request. If such documentation in written form is kept in a location other than the production and control record for the particular production aggregate, there is no way to review the entire production process during manufacture without retrieving all of the critical information from other records and storage locations. Similarly, if electronic records are not properly linked, neither the producer nor FDA will have prompt access to such records. Accordingly, FDA is clarifying the proposed requirement in § 106.100(e) of the interim final rule in response to this comment, by amending § 106.100(m) of the interim final rule to explain that all records, no matter what their form, must be maintained in a way that allows for immediate access.

1. Master Manufacturing Order Records

(Comment 302) One comment objected to the requirement in proposed § 106.100(e)(1)(ii) that where a manufacturing facility has more than one set of equipment or more than one processing line, the master manufacturing order identify the equipment and processing lines used in making a particular batch (production aggregate). The comment suggested that this provision be revised to require that, in such circumstances, the master manufacturing order include the identity of only the major equipment systems used in producing the batch (production aggregate). The comment argued that it is reasonable to require the identity of major equipment systems, such as processing systems and filling lines, if more than one is available; however, it is not reasonable to expect every piece of processing equipment, such as every transfer line, hook-up station, jumper, and valve, to be identified in the production records. The comment noted that infant formula manufacturing involves multitudes of equipment pieces and lines, so the itemization of these for every batch (production aggregate) would require significant resources with no practical benefits.

(Response) FDA is not persuaded to revise § 106.100(e)(1)(ii) to limit the subject equipment to "major equipment systems" because doing so may exclude equipment that, while not "major," may, in the event of a malfunction or contamination, be implicated nonetheless in the adulteration of an infant formula. The purpose of this requirement is in part to facilitate the identification of all production aggregates of formula that may be affected by a particular instance of equipment malfunction or that were produced on the same equipment as a production aggregate that is discovered to be microbiologically contaminated (61 FR 36154 at 36190). To achieve this purpose, a manufacturer must identify such equipment and processing lines to ensure, for example, that any equipment malfunctions that adulterate or may lead to adulteration of the infant formula can be linked to any implicated production aggregates of infant formula, which will facilitate a material review and disposition decision and appropriate corrective action. Similarly, it would be important to identify in the production aggregate record any equipment components that could be a source of adulteration but would not be readily

identified from the piece of equipment used.

Although FDA is not making the revision requested by this comment, the Agency is adding a phrase to § 106.100(e)(1)(ii) in the interim final rule to clarify that records of the identity of the equipment and processing lines only need to be kept for the equipment and processing lines for which the manufacturer has identified points, steps, or stages in the production process where control is necessary to prevent adulteration. Thus, § 106.100(e)(1)(ii) of the interim final rule states: "For a manufacturing facility that has more than one set of equipment or more than one processing line, the identity of equipment and processing lines for which the manufacturer has identified points, steps, or stages in the production process where control is necessary to prevent adulteration."

(Comment 303) One comment requested that proposed § 106.100(e)(1)(v) be revised to delete the requirement that the master manufacturing order include copies of all labeling and substitute a requirement that the master manufacturing order include copies of all primary container labels used and the results of examinations during finishing operations to provide assurance that containers and packages have the correct label. The comment agreed with the requirement to include a sample of the primary container label in each batch (production aggregate) record, but asserted that including trays, cartons, and shippers that are also considered labeling would substantially increase the size of the batch (production aggregate) record because the trays, cartons, and shippers are relatively bulky.

(Response) FDA agrees that it is adequate to include in the master manufacturing order record only a copy of the labeling used on the immediate container of the finished production aggregate of infant formula. Such labels are usually distinctive in appearance and, unlike trays, cartons, and shippers, generally are the labeling on which consumers rely when purchasing and using a formula. FDA notes that, by definition, the word "label" is written, printed, or graphic matter affixed to the immediate container of a product. 21 U.S.C. 321(k). Accordingly, FDA is modifying § 106.100(e)(1)(v) in the interim final rule to require that the master manufacturing order include a copy of each label used on a finished production aggregate of infant formula and the results of examinations conducted during the finishing operations to provide assurance that all containers have the correct label.

(Comment 304) One comment objected to the use of the phrase "corrective actions" in proposed § 106.100(e)(2), (e)(3)(ii), and (e)(4)(i) and requested that the phrase be replaced with "specific actions" in each of these sections. The comment argued that, due to timing, it is not always practical to include corrective actions in the same batch (production aggregate) record as the documentation of deviations. The comment explained that if the corrective action is immediate, it would be reasonable to include documentation of the corrective action in the batch (production aggregate) record. However, the comment contended, it is impractical to include the corrective action when the deviation requires investigation and research over an extended period of time or involves the evaluation of multiple batches (production aggregates) before the appropriate corrective action is identified. In these cases, the comment maintained, it would be impractical to place a copy of the corrective action taken into the record of each affected batch (production aggregate) after the fact but it would be sufficient to require documentation of the manufacturer's response to each deviation in its respective batch (production aggregate) record. The comment argued that this action would include responses to the deviations, if immediately known, or a statement of the need for further evaluation, or some other appropriate indication of the status of the investigations or corrective action.

(Response) FDA is not persuaded by this comment because it ignores the role of production records, including records of corrective actions, in ensuring the safety of infant formula.

In the preamble to the 1996 proposal, FDA discussed why these records must appear in the production aggregate production and control record (61 FR 36154 at 36190–36191). These records have a critical role helping the manufacturer to ensure that the infant formula is in compliance with the CGMP requirements for infant formula and to ensure that any deviation that has occurred during the production of the infant formula will not adulterate or lead to adulteration of the product. A manufacturer must not release a finished production aggregate of infant formula until it determines that the production aggregate meets all of its specifications, or until the documented review of the failure to meet any of the manufacturer's specifications finds that the failure does not result in, or could not lead to, adulteration of the product (*see* § 106.70(a) of the interim final rule). A manufacturer would need to determine what, if any, specifications are or may not be met and otherwise address a deviation from the master manufacturing order before the production aggregate of infant formula is released for distribution. Thus, any determination of how to handle a deviation will occur during the time period when the production and control record is being prepared. Once a manufacturer has determined how to handle a deviation from specifications, any corrective action shall be recorded and that record made part of the production aggregate record at that time.

Furthermore, if a deviation is noted in the production and control record for the production aggregate, documentation of any corrective action taken must appear in the production aggregate record to make it complete and to ensure that the deviation was appropriately investigated and addressed. Therefore, documentation of any corrective action(s) taken is appropriately part of the production and control record for the production aggregate to provide a basis for the ultimate decision to release (or not release) the production aggregate for distribution. Because the record of a corrective action is part of the history of a particular production aggregate, this documentation should not be maintained in another record or location that is not linked directly and closely to the production of the particular production aggregate of infant formula. In addition, the comment provided no rationale for why FDA should use the term "specific actions" instead of "corrective actions." For these reasons, FDA is not revising proposed § 106.100(e)(2), proposed § 106.100(e)(3)(ii), and proposed § 106.100(e)(4)(i) in response to this comment, and these provisions are included in this interim final rule as proposed.

2. Records of the Production and In-process Control System

(Comment 305) One comment suggested revising proposed § 106.100(e)(3) by changing the term "necessary" to "critical" and thus requiring that documentation be included where control is deemed critical to prevent adulteration.

(Response) FDA is not persuaded by this comment. As discussed previously in this document in section IV.C.8, FDA is not persuaded that the word "critical" enhances the clarity of the phrase "necessary to prevent adulteration." Therefore, FDA is not revising proposed § 106.100(e)(3) in response to this

comment, and this provision is included in this interim final rule as proposed.

(Comment 306) One comment suggested that proposed § 106.100(e)(4)(i) be revised to state "any deviation from the manufacturing order and any specific action taken to adjust or correct a batch [production aggregate] in response to a deviation," and that, as a result, proposed § 106.100(e)(4)(iii) could be deleted as redundant. (Proposed § 106.100(e)(4)(iii) would require that the batch (production aggregate) production and control record contain the conclusions and followup, along with the identity, of the individual qualified by training or experience who investigated a failure to meet any standard or specification at any point, step, or stage in the production process where control is necessary to prevent adulteration.)

(Response) FDA declines to make the suggested revisions to § 106.100(e)(4) in the interim final rule. The comment did not provide a reasoned basis for substituting the term "specific action" for "corrective action" or for inserting the phrase "to adjust or correct a batch in response to a deviation" to describe the corrective actions taken. Further, FDA disagrees that § 106.100(e)(4)(iii) would be redundant with proposed § 106.100(e)(4)(i) even if the latter provision were revised as suggested. The scope of proposed § 106.100(e)(4)(i) and proposed § 106.100(e)(4)(iii) are very different. Proposed § 106.100(e)(4)(i) covers only deviations from the master manufacturing order. (A master manufacturing order provides the plan for manufacture of the infant formula.) In contrast, proposed § 106.100(e)(4)(iii) relates to the investigation of a failure to meet any specification in the production process where control is deemed necessary to prevent adulteration, a provision that extends to the entire production process, including a deviation from the master manufacturing order and a deviation from any part of the manufacturing process, such as a deviation from the provisions of proposed §§ 106.10, 106.20, 106.30 106.35 or 106.40. Accordingly, FDA is not revising § 106.100(e)(4) as requested in this comment.

3. Records on Production Aggregate (Batch) Testing

(Comment 307) One comment objected to the stability testing record requirements in proposed § 106.100(e)(5), which would require that the batch (production aggregate) production and control record include records of the results of all testing performed on the batch (production aggregate) of infant formula, including testing on the in-process product, at the final product stage, and on finished product throughout the shelf life of the product. The comment argued that the requirement to include all stability test results in the individual batch (production aggregate) records is an additional administrative burden and can easily be avoided by requiring that shelf life testing results be made available to the Agency upon request, either by outside communication or through inspection. The comment stated that if a requirement were made to store the data with the manufacturing work order, an additional system would need to be developed to link the data at an additional cost with no commensurate benefit to public health.

(Response) FDA is not persuaded that requiring all stability testing results to be included in the production aggregate production and control record would be an unwarranted administrative burden to formula manufacturers. FDA notes that the comment's concern was limited to the administrative burden of maintaining stability records in the production and control record and did not explain why stability testing records are different from all other testing records in terms of such burden.

The principle underlying proposed § 106.100(e)(5) is that all testing records that relate to a specific production aggregate (batch) must be co-located (or linked electronically) so that, should there be an adulteration concern about a particular production aggregate, both the manufacturer and FDA can have immediate access to all relevant testing records for the formula in question. Also, maintaining stability testing records in the production and control record will help avoid duplication. This is because the final product testing that would be required by proposed § 106.91(a)(4) may also serve as the initial (baseline) stability testing.

The Agency acknowledges that, with the exception of initial stability testing, all stability testing is likely to occur after the finished infant formula has been released for distribution, and the production and control record for a production aggregate is likely to be established at or near the time the formula is manufactured. However, it is not unreasonable to require stability testing records to be co-located (for hard copy records) or electronically linked (for electronic records) with the production aggregate production and control record and that any records created post-distribution may simply be added to or linked with the production and control record. As noted, the comment did not distinguish stability testing records from other production records that this interim final rule requires to be maintained in the production aggregate production and control record. Absent such distinction, it is entirely reasonable that stability testing records be maintained with other records relating to a particular production aggregate.

Moreover, as discussed in section VI. Quality Control Procedures, stability testing of finished infant formula is critical because it evaluates whether all nutrients (both those required by § 107.100 and those otherwise added by the manufacturer) are present in the formula at the desired level throughout the formula's shelf life. A formula that lacks one or more of these nutrients at the appropriate level may be unable to support normal growth of the infants consuming it as their sole source (or virtually sole source) of nutrition. Similarly, the records of stability testing of a particular production aggregate are an integral part of the history of the particular production aggregate of formula and, like other production records that supply the history of a production aggregate, these stability testing records need to be immediately accessible to both the manufacturer and FDA. For these reasons, FDA declines to revise § 106.100(e)(5) in response to this comment.

(Comment 308) Another comment suggested that because the results of stability testing should be required as a part of the good manufacturing practice records instead of as a part of the batch (production aggregate) production and control records, the summary of results from the stability testing program required by proposed § 106.100(e)(5)(i)(B) should be incorporated into the good manufacturing practice records.

(Response) FDA disagrees with this comment. As outlined in the preceding response, records of stability testing are part of the manufacturing history of the particular production aggregate and, as such, are reasonably required to be maintained in the production aggregate production and control record. The summary of such testing required by § 106.100(e)(5)(i)(B) of the interim final rule is appropriately maintained as part of the same production and control record. Thus, FDA is not making any revisions in response to this comment.

(Comment 309) One comment suggested that FDA revise both proposed § 106.100(e)(5)(i)(A), which would require a summary table identifying the stages of the manufacturing process at which the manufacturer conducts the nutrient analysis required under proposed

§ 106.91(a) for each required nutrient, and proposed § 106.100(e)(5)(i)(B), which would require a summary table of the stability testing program that would be required under proposed § 106.91(b), including the nutrients tested and the testing frequency for nutrients throughout the shelf life of the product. The comment suggested that "table" should be changed to "document" because "document" implies a reference best suited to the manufacturer's system, as opposed to a specific type of a reference, such as table.

(Response) FDA agrees with this comment. It is reasonable to provide formula manufacturers with flexibility to create a summary document so long as the chosen format accurately and succinctly conveys the data identified as appropriate in proposed § 106.91(a) and proposed § 106.91(b). The summary document may, but is not required to, be in the form of a table, if the manufacturer determines that such format is a convenient and accurate summary document. Thus, in response to this comment FDA is modifying both § 106.100(e)(5)(i)(A) and (e)(5)(i)(B) by changing the word "table" to "document."

C. Records of CGMP (Proposed § 106.100(f))

FDA did not receive any comments requesting modification of proposed § 106.100(f)(1) and proposed § 106.100(f)(3). Thus, these provisions are included in this interim final rule as proposed. FDA received a comment on proposed § 106.100(f)(2), which suggested that the words "standards" be omitted from that provision. As discussed previously in this document, the Agency agrees generally with this comment and has revised several provisions in this interim final rule, including proposed § 106.100(f)(2), by deleting "standard or."

1. Records on Equipment and Utensils

(Comment 310) One comment objected to the inclusion of the "lot number" in proposed § 106.100(f)(4), which would require that records be maintained, in accordance with proposed § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show, among other things, the lot number of each batch (production aggregate) of infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. Proposed § 106.100(f)(4) also would require the person performing and checking the cleaning, sanitizing, and maintenance to date and sign or initial the record indicating that the work was performed. The comment contended that the requirement to document all lot numbers of batches (production aggregates) produced between all equipment cleaning, sanitizing, and maintenance is an overwhelming administrative requirement that is unnecessary on a daily basis. The comment asserted that the records should have sufficient detail and reference points (e.g., time, location) to allow reconstruction of this type of information if needed, but to require it routinely serves no purpose.

(Response) FDA disagrees. Accurate recordkeeping on equipment cleaning, sanitizing, and maintenance showing the date and time of such activities will provide a means by which the manufacturer can ensure that equipment is being cleaned and maintained regularly and that the frequency of such cleaning is appropriate in light of the actual use of the equipment. Moreover, records that identify the production unit number or production aggregate number (see § 106.3 of the interim final rule) of each production unit or production aggregate of infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance are essential in situations of equipment contamination because such records will permit a manufacturer to determine which production units or production aggregates of infant formula are or may be adulterated. Thus, the requirements of § 106.100(f)(4) are both reasonable and critical to the production of safe infant formulas.

FDA is not persuaded that § 106.100(f)(4) should be modified because other records could be used to reconstruct this information, if needed. The most reliable and accurate way to develop this type of information is to create an appropriate record in real time for this specific purpose. Maintaining this type of information would be particularly important when equipment maintenance, planned or unplanned, might have an impact on infant formula production aggregates produced between the previous maintenance and the time the equipment was repaired. In such a case, it may be necessary for a firm to investigate and identify which production aggregates were manufactured between those time periods. These records will complement the production aggregate production and control records and will facilitate a manufacturer's trace back to all potentially affected production units or production aggregates when there is an instance of an equipment failure that might result in an adulterated product (e.g., microbiological contamination). Therefore, FDA is not revising proposed § 106.100(f)(4) in response to this comment, and this provision is included in this interim final rule, with minor editorial changes, as proposed.

2. Records on Automatic Equipment

(Comment 311) One comment suggested, consistent with the comment's recommendation that proposed § 106.35 be deleted, the deletion of proposed § 106.100(f)(5), which relates to records on automatic (mechanical or electronic) equipment required in accordance with proposed § 106.35(c).

(Response) As discussed previously in this document in section V.G, FDA does not agree that proposed § 106.35 should be eliminated. As noted in that discussion, the Agency has clarified the application of validation to the manufacture of infant formula. Because the comment provides no independent basis for deleting proposed § 106.100(f)(5), FDA declines to eliminate the recordkeeping requirements of proposed § 106.100(f)(5) in response to this comment.

(Comment 312) One comment suggested that proposed § 106.100(f)(5)(i), which requires a list of all systems used with a description of computer files and the inherent limitations of each system, be revised to require a list of all systems used with a description of computer files and the defined capabilities of each system. The comment asserted that the range in capability of a system is a better description than the inherent limitations of a system and would include at least the same information.

(Response) FDA disagrees that providing the defined capabilities of each system would provide a better description of the system rather than a description of the system's inherent limitations. The purpose of proposed § 106.100(f)(5)(i) is to require that the records for automatic equipment include a sufficiently detailed description of the system to enable the manufacturer to operate and troubleshoot the system. The Agency disagrees that a description of the defined capabilities of a system would include the same information as a description of the inherent limitations of a system. A description of the defined capabilities of a system identifies what the system is designed to do while a description of the system's inherent limitations identifies what the system is incapable of doing. Upon further consideration, FDA has determined that in order for a manufacturer to operate and troubleshoot a system, it is essential that a manufacturer's records include a description of both the defined capabilities and inherent limitations of

the system. Accordingly, FDA is revising § 106.100(f)(5)(i) to require "A list of all systems used with a description of the computer files and the defined capabilities and inherent limitations of each system."

(Comment 313) One comment on proposed § 106.100(f)(5)(vii) asserted that hard copy recording should be reduced to a minimum and attempts made to ensure that all key process results are obtained electronically because the latest instruments automatically record to a computer with data processing, graphing, and alarm signals produced instantaneously. The comment claimed that back-up methods can eliminate fears of data loss so there is now no need for burdensome recording better suited to the last century.

(Response) FDA agrees that technology has changed since publication of the proposal and has made modifications to the interim final rule to permit the use of back-up systems that may become available in the future as well as those systems currently in use. Specifically, FDA is revising § 106.100(f)(5)(vii) to delete the reference to specific older storage systems (e.g., diskettes) and to substitute the term "electronic records." This will provide a manufacturer with the option to use newly developed technologies, if the manufacturer chooses to do so. Thus, § 106.100(f)(5)(vii) of the interim final rule requires "A backup file of data entered into a computer or related system. The backup file shall consist of a hard copy or alternative system, such as duplicate electronic records, tapes, or microfilm, designed to ensure that backup data are exact and complete, and that they are secure from alteration, inadvertent erasures, or loss."

D. Records on Infant Formula for Export Only (Proposed § 106.100(g))

(Comment 314) One comment requested clarification of proposed § 106.100(g), which requires that the manufacturer maintain all records pertaining to distribution of an infant formula, including records showing that products produced for export only are exported. The comment stated that it is reasonable to expect a manufacturer to maintain distribution records regarding shipment of infant formula under the manufacturer's control. However, the comment contended that once the infant formula is in the hands of the retailer, customer, consumer, or exporter, the manufacturer can no longer be responsible for obtaining or keeping these records and should not retain that responsibility after the infant formula has left its control. The comment also stated that sometimes manufacturers ship infant formula to a customer who, in turn, intends it only for export. Because the manufacturer is not responsible for the actual export, the manufacturer would have no records regarding distribution of such infant formula after it is turned over to the exporter.

(Response) FDA agrees that an infant formula manufacturer must maintain distribution records regarding shipment of infant formula under the manufacturer's control, including records of shipments to a manufacturer's consignees. Such distribution records are routinely maintained by manufacturers. Thus, if a consignee is a foreign purchaser, the manufacturer would have records of shipment to such consignee. A sale of infant formula for export only directly to a foreign purchaser would be consistent with the requirement in section 801(e)(1)(D) of the FD&C Act (21 U.S.C. 381(e)(1)(D)) that a product not be "sold or offered for sale in domestic commerce," provided that the product is, in fact, exported. In contrast, if a manufacturer sells an infant formula to a distributor in the U.S., the manufacturer would not be in compliance with section 801(e)(1)(D) of the FD&C Act because this transaction would involve the sale (or the offer for sale) of the infant formula in domestic commerce. FDA recognizes that, in some cases, however, a manufacturer may transfer an infant formula to a domestic third-party (e.g., contractor or other agent of the manufacturer) who, on behalf of the manufacturer, exports the product to a foreign consignee. This latter transaction would not be considered a "sale" of the infant formula in domestic commerce for the purposes of section 801(e)(1)(D) of the FD&C Act because there is no transfer of ownership to the third-party acting on behalf of the manufacturer. In such situation, FDA expects that the manufacturer would have access to the records of export of such third-party. Therefore, where the manufacturer ships its product to a foreign consignee, either directly or through a third-party who ships such product to a foreign consignee, the manufacturer would have the necessary access to distribution records (e.g., bill of lading) showing that the infant formula produced for export only is actually exported. The distribution records are required under section 412(g) of the FD&C Act and are required by current § 106.100(l) to be available for inspection. FDA notes that these and other records may also be required under 21 CFR 1.101(b)(4) for foods, in general, that are for export only.

For the foregoing reasons, FDA is only making minor editorial changes to § 106.100(g).

In the proposed rule, FDA expressed concerns about infant formulas produced for export only that are diverted and sold in the United States (61 FR 36154 at 36194). Proposed § 106.100(g) was intended, in part, to be a means to verify that the infant formula was not in fact sold or offered for sale in domestic commerce. *Id.* A manufacturer of an infant formula for export only has a responsibility under section 801(e)(1)(D) of the FD&C Act and section 412(b)(2) of the FD&C Act to ensure that it or any third-party acting on its behalf exports the infant formula for export only and does not divert it for sale in domestic commerce. As noted previously in this document, under section 801(e) of the FD&C Act, an infant formula for export only is deemed not to be adulterated or misbranded if the formula satisfies the criteria in section 801(e) of the FD&C Act, including that it is not sold or offered for sale in domestic commerce. In order to move such a product lawfully in interstate commerce, the manufacturer must take the necessary steps to ensure that the product complies with section 801(e) of the FD&C Act. *See United States* v. *Parfait Powder Puff Co.*, 163 F.2d 1008, 1010 (7th Cir. 1947) (explaining that "one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law, if the nonperformance of such duty is a crime"). Further, a manufacturer of infant formula for export only, which formula is otherwise adulterated or misbranded under U.S. law, has an obligation under section 412 of the FD&C Act to establish adequate controls under CGMP respecting the distribution of such product to ensure that adulterated product is not sold or offered for sale in domestic commerce.

Section 412(d) of the FD&C Act requires a formula manufacturer to make certain submissions that provide assurances that the firm's formula is not adulterated. FDA is not requiring, under the requirements in § 106.120 of the interim final rule for new infant formula submissions, that a manufacturer of infant formula for export only submit the same information that would be required for a formula intended or offered for sale in domestic commerce. Instead, to meet the requirements in

sections 412(d)(1)(C) and (D) of the FD&C Act and § 106.120 of the interim final rule, such a manufacturer may provide assurances that include, among other commitments, that the infant formula will not be sold or offered for sale in domestic commerce, consistent with section 801(e) of the FD&C Act. In addition, to ensure that a manufacturer takes the necessary precautions to prevent an infant formula it distributes for export only from being diverted for sale in domestic commerce, FDA is requiring in this interim final rule, as part of the submission requirements in § 106.120(c) of the interim final rule, that a manufacturer of infant formula for export only certify that it has adequate controls in place to ensure its formula for export only is actually exported (see discussion in section X.C.3 for § 106.120(c) of the interim final rule). In making this certification, the manufacturer is assuring that the product will not be sold or offered for sale in domestic commerce and thereby meets the requirements of the FD&C Act under sections 412(d)(1)(C) and (D) that, if not met, would result in the formula being deemed adulterated under sections 412(a)(2) and (3) of the FD&C Act.

E. Means of Recordkeeping (§ 106.100(m))

(Comment 315) One comment recommended that the final regulation reflect the acceptability of electronic recordkeeping.

(Response) FDA agrees that it may be appropriate to use electronic recordkeeping to meet the requirements of § 106.100, provided that the records are maintained in accordance with part 11 (21 CFR part 11). Part 11 applies to any electronic records that are maintained to comply with the requirements of this interim final rule. The Agency advises that the use of electronic records is voluntary and thus, a paper record system may be used to comply with these recordkeeping requirements. In response to this comment, FDA is revising § 106.100(m) to state that records required under part 106 may be retained as original records, as true copies of the original records in a form such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records, or as electronic records. In addition, FDA is modifying § 106.100(m) to require all electronic records maintain under part 106 to comply with part 11.

The requirements for electronic records extend to electronic signatures. FDA has issued final guidance for industry on this topic. The guidance entitled "Part 11, Electronic Records; Electronic Signatures Scope and Application" sets out the Agency's enforcement policies with respect to certain aspects of part 11. The guidance is available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm.* This guidance applies to any electronic record, including electronic signatures, established or maintained to meet a requirement in this interim final rule.

F. Records of Quality Factors (§ 106.100(p) and (q))

For consistency with other records requirements, FDA is adding two new provisions to § 106.100 of the interim final rule to clarify the requirements for making and retaining records that demonstrate that an infant formula meets the quality factor requirements. All of the records requirements for part 106 are located in subpart F. Therefore, for comprehensiveness and clarity, FDA is adding language to § 106.100 in the interim final rule to include the recordkeeping requirements for quality factors.

As is discussed in section VIII.I, the interim final rule contains the requirement that an infant formula manufacturer make and retain records demonstrating that such formula meets the quality factors requirements. Section VIII.I also explains that, although both "eligible" and non-eligible formulas will be required to meet the quality factors of normal physical growth and sufficient biological quality of protein, "eligible infant formulas" will be able to use separate established criteria to demonstrate compliance with those quality factors. As such, these new provisions in subpart F describe the separate quality factor records requirements for eligible formulas and non-eligible formulas. For a formula that is not an eligible formula, the manufacturer of the formula must make and retain records that demonstrate compliance with the requirements in § 106.96(b) and (f) of the interim final rule, or, as applicable, an exemption to either provision. An eligible formula manufacturer must make and retain records that demonstrate compliance with the requirements in § 106.96(i)(1) and (i)(2) of the interim final rule.

G. Adulteration as a Consequence of the Failure To Keep Records (§ 106.100(r))

For clarity, FDA is also adding a paragraph to § 106.100 in the interim final rule that discusses when an infant formula will be considered adulterated for the failure to make or retain a record.

As noted, the records requirements in part 106 are located in subpart F. However, despite the fact that these records provisions are located in subpart F, many of these records are considered to be a current good manufacturing practice, quality control procedure, or quality factor requirement. For example, § 106.100(e)(3) of the interim final rule requires records documenting the monitoring at any point, step, or stage in the manufacturer's production process where control is deemed necessary to prevent adulteration. Such monitoring is a part of good manufacturing practices. Thus, although the substance of the recordkeeping requirement to make and retain records of this practice is located in subpart F, § 106.100(e)(3) of the interim final rule is also a part of current good manufacturing practices.

Because some of the requirements in subpart F are a part of the current good manufacturing practices, quality control procedures, and quality factor requirements, the failure to follow some of the requirements in subpart F will necessarily adulterate the infant formula. The failure to follow any CGMP or quality control requirement will adulterate the formula under section 412(a)(3) of the FD&C Act. Likewise, the failure to follow any quality factor requirement will adulterate the formula under section 412(a)(2) of the FD&C Act.

X. Subpart G—Registration, Submission, and Notification Requirements

In the 1996 proposed rule, FDA proposed a new subpart G to establish requirements for registration by an infant formula manufacturer (implementing section 412(c)(1)(A) of the FD&C Act), submission of information relating to a new infant formula (implementing section 412(d) of the FD&C Act), and notification relating to any adulterated or misbranded infant formula that has left the control of a manufacturer (implementing section 412(e) of the FD&C Act.) The 2003 reopening requested comments on all aspects of the 1996 proposal, including proposed Subpart G.

FDA received comments on a number of the provisions in proposed subpart G. The Agency's responses are set out in this document.

A. General Comments

Several comments stated that the premarket notification requirements of section 412(c) and (d) of the FD&C Act do not constitute a premarket approval process for infant formula and cited legislative history in support of their assertion.

(Comment 316) One comment stated that FDA's role in the premarket notification process was perceived by Congress as comprising the task of confirming that the required [nutrient] specifications are met for each new or significantly modified formula.

(Response) FDA disagrees with the comment to the extent that it suggests that FDA's role in the premarket notification process is limited to confirming that the FD&C Act's nutrient specifications are met. In fact, through the premarket notification process in section 412 of the FD&C Act, Congress assigned FDA a comprehensive role in evaluating new infant formulas. As noted in the 1996 proposal, the FD&C Act requires that the manufacturer of a new infant formula submit a variety of information on the new infant formula, including information on its quantitative composition, on any reformulation, on any changes in processing, assurances that quality factor requirements have been met, assurances that the nutrient requirements have been met, and assurances that the manufacturing adhere to CGMP and quality control procedures. All of this information is reviewed by the Agency to ensure that the infant formula will be a safe product that adheres to all applicable laws and regulations.

(Comment 317) Another comment asserted that, over the years, the practices and procedures FDA has followed in reviewing notifications under section 412 of the FD&C Act have consistently taken on more and more of the trappings of premarket approval systems quite different from the limited, precise review function contemplated in the statutory scheme.

(Response) As explained in the previous response, FDA disagrees that the Agency's review role under section 412 of the FD&C Act is a narrow one. In addition, the comment did not provide any underlying details to explain its assertion that FDA's review procedures have "taken on the trappings of premarket approval systems."

Accordingly, the Agency is making no changes to the rule in response to Comments 316 and 317.

(Comment 318) One comment requested that the Agency establish and make public a well-defined, transparent, and practical process for the receipt, review, and disposition of various infant formula submissions from industry. The comment suggested that the process include review time lines, the definition of the review process, the identification of reviewers, and a response and dialogue process, and asserted that such process definition is necessary for industry planning and implementation of infant formula advancements in a mutually cooperative manner.

(Response) FDA disagrees in part with this comment. The interim final rule provides a well-defined, transparent, and practical process for the receipt and review of the infant formula submissions required by section 412 of the FD&C Act. The interim final rule clearly identifies the information that must be provided to FDA in the various submissions, the form in which it is to be submitted, and where the information is to be submitted. Under the FD&C Act, a manufacturer must make a submission to FDA at least 90 days before marketing a new infant formula.

FDA does not agree that certain matters should be made available to the public, as suggested by the comment. In particular, review time lines, a description of the review process, and the identification of Agency reviewers are all internal administrative management items and are not relevant to a manufacturer's obligations or responsibilities under the FD&C Act. Indeed, the comment itself did not explain why formula manufacturers need such information. Accordingly, the interim final rule does not commit FDA to disclosing these types of details.

B. New Infant Formula Registration (Proposed § 106.110)

In 1996, FDA proposed to establish requirements to implement section 412(c)(1)(A) of the FD&C Act. Specifically, FDA proposed in § 106.110 that, before a new infant formula may be introduced or delivered for introduction into interstate commerce, the manufacturer of such formula must register with FDA and provide the name of such formula, the name of the manufacturer, the manufacturer's place of business, and all establishments at which the manufacturer intends to manufacture such formula.

The Agency responds in this document to the comments received on proposed § 106.110.

(Comment 319) One comment suggested that FDA revise proposed § 106.110 on new infant formula registration to require that manufacturers of infant formula for export register with FDA. The comment suggested revising § 106.110 to include the requirement that infant formula products for export only comply with section 801(e) of the FD&C Act and deleting the requirement in § 106.120(c), a revision that would, the comment asserted, reduce the time and expense for preparing and reviewing submissions for infant formula intended for export.

(Response) FDA agrees that the interim final rule should require a manufacturer of an infant formula product intended for export only to register with FDA. Section 412(c)(1)(A) of the FD&C Act requires that no person shall introduce or deliver for introduction into interstate commerce any new infant formula unless such person has registered with the Secretary (and by delegation, FDA). The act of exporting infant formula necessarily requires the introduction or delivery for introduction into interstate commerce of the formula. Infant formula manufactured for export only may nonetheless be a "new infant formula" as defined in § 106.3 of the interim final rule. Therefore, FDA is revising § 106.110(a) in the interim final rule to clarify that a manufacturer who produces formula for export only is required to register with FDA. The Agency is also revising § 106.110(a) to update the contact information for FDA's Center for Food Safety and Applied Nutrition. Thus, § 106.110(a) of the interim final rule states "Before a new infant formula may be introduced or delivered for introduction into interstate commerce, including a new infant formula for export only, the manufacturer of the formula shall register with the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HSF–850), 5100 Paint Branch Pkwy., College Park, MD 20740–3835."

The Agency disagrees that proposed § 106.110 should be revised to require that infant formula products intended for export comply with section 801(e) of the FD&C Act and that proposed § 106.120(c) be deleted for the reasons the comment provided. A manufacturer of an infant formula for export only must still provide a submission under sections 412(c)(1)(B) and (d)(1) of the FD&C Act. Section 412(c)(1)(B) of the FD&C Act requires that no person shall introduce or deliver for introduction into interstate commerce any new infant formula unless such person has at least 90 days before marketing such new infant formula made the submission required under the FD&C Act. The failure to provide notice under section 412(c) of the FD&C Act, including the submission in section 412(d)(1) of the FD&C Act, is a prohibited act under section 301(s) of the FD&C Act (21 U.S.C. 331(s)). However, as is explained in response to Comment 328, FDA is revising § 106.120(c) in the interim final

rule to clarify the assurances that must be provided for infant formula for export only.

(Comment 320) One comment suggested that proposed § 106.110(b)(4), which would require that the new infant formula registration include all establishments at which the manufacturer intends to manufacture such new infant formula, be revised to require the name and addresses of all establishments at which the manufacturer intends to manufacture such new infant formula.

(Response) FDA agrees with this comment. The name and address of the establishments is a necessary component of the registration and will allow the Agency to identify and locate each establishment; only if FDA can locate an establishment can the Agency inspect such firms and otherwise carry out its regulatory responsibilities. Therefore, § 106.110(b)(4) of the interim final rule requires that the new infant formula registration include the name and street address of each establishment at which the manufacturer intends to manufacture a new infant formula.

C. New Infant Formula Notifications (Proposed § 106.120)

In 1996, FDA proposed to establish requirements to implement section 412(c)(1)(B) and 412(d)(1) of the FD&C Act. Specifically, FDA proposed in § 106.120 that at least 90 days before the interstate distribution of a new infant formula, a manufacturer submit certain information to FDA pertaining to the new infant formula.

FDA received a number of comments on proposed § 106.120 and responds in this document to those comments.

1. Form of Submission (Proposed § 106.120(a))

The proposed rule, § 106.120(a), would have required that an original and two copies of a new infant formula submission be provided to FDA. As discussed previously in this document, in response to a comment, § 106.100(m) of the interim final rule permits a manufacturer to maintain records as original paper records, as true copies of the originals (e.g., microfilm), or as electronic records. Such electronic records are required to conform to 21 CFR Part 11. Consistent with this revision, FDA is, on its own initiative, revising § 106.120(a) in the interim final rule to permit new infant formula submissions to be submitted electronically and, in such case, to require only a single copy of such electronic submission. Thus, § 106.120(a) of the interim final rule states, "At least 90 days before a new infant formula is introduced or delivered for introduction into interstate commerce, a manufacturer shall submit notice of its intent to do so to the Food and Drug Administration at the address given in § 106.110(a). An original and two paper copies of the notice of its intent to do so shall be submitted, unless the notice is submitted in conformance with part 11 of this chapter, in which case, a single copy shall be sufficient."

2. Contents of a New Infant Formula Submission (Proposed § 106.120(b))

Proposed § 106.120(b) would have established the required contents of a new infant formula submission. FDA received comments on a number of the provisions of proposed § 106.120(b), and responds in this section.

a. *Quantitative formulation (Proposed § 106.120(b)(3)).*

(Comment 321) One comment questioned the requirement in proposed § 106.120(b)(3) that the quantitative formulation of the new infant formula be submitted in units per volume for liquid formulas. The comment asserted that formulations are routinely listed and have traditionally been submitted to the Agency in units per weight of liquid. The comment also requested clarification of the volume units to use in the quantitative formulation and whether the information should be provided on an "as sold" or "as fed" basis in the submission.

(Response) The Agency has examined previously received infant formula submissions and determined that the formulations of liquid formulas have been provided to the Agency in either units per weight (e.g., milligrams/kilogram) or in units per volume (e.g., milligrams/liter). Accordingly, the interim final rule, at § 106.120(b)(3), permits a manufacturer to provide the quantitative formulation of a new infant formula either in units per weight or units per volume, and on an "as sold" or "as fed" basis, provided that the manufacturer specifies whether the quantitative formulation is on an "as sold" or "as fed" basis. For a powdered infant formula, the submission must also specify the weight of powder to be reconstituted in a specific volume of water (e.g., grams (g) of powder per fluid (fl) ounce (oz) of water).

(Comment 322) One comment requested clarification on whether FDA requires a table of nutrients as well as a table of ingredients as part of the quantitative formulation.

(Response) The interim final rule does not require a manufacturer to submit a table reflecting the amount of various nutrients in an infant formula formulation as part of the requirement to provide the quantitative formulation. FDA is taking this opportunity to clarify that the "quantitative formulation" required by section 412(d)(1)(A) and (d)(3) of the FD&C Act is a list of all ingredients (including individual ingredients and premixes of two or more ingredients) in a product and the amount by weight of each ingredient in a set volume or weight of the formula. For example, several ingredients in an infant formula formulation may contain calcium. Thus, the quantitative formulation would identify each individual ingredient (e.g., calcium phosphate, calcium carbonate, calcium hydroxide) and the amount (by weight or volume) of each ingredient. For mineral salts, the state of hydration must be provided because the amount of water contained in the salt affects the amount of mineral (e.g. calcium) provided. For vitamins, the source of the vitamin (e.g., vitamin A palmitate or vitamin A acetate) must be provided because the proportion of vitamin differs with each source.

If a nutrient is added to the formulation as a part of a premix, the form of the nutrient and the amount the nutrient must be provided (listed) as part of the premix information.

Not all sources of nutrients may be readily apparent in quantitative formulations, as some nutrients may be endogenous to certain ingredients (e.g., calcium and phosphorous in condensed skim milk). In such a case, the identity and amount of the ingredient (e.g., the condensed skim milk) is required to be listed in the quantitative formulation—the amounts of endogenous nutrients (e.g., the calcium and phosphorus contained in the condensed skim milk) would also need to be provided, and their listing is analogous to the listing requirement for premixes.

Although not required by the interim final rule, including a separate table of nutrients per 100 kcal in the submission will help to expedite FDA's review of the new infant formula submission.

FDA notes that under § 106.130 of the interim final rule, a manufacturer is required to provide in the verification submission for a new infant formula the level of all nutrients contained in the formula product that reflect the analysis of the product at the finished product stage.

b. *Description of a change in processing (Proposed § 106.120(b)(4)).*

(Comment 323) One comment objected to the requirement of proposed § 106.120(b)(4) that the description of any change in processing of the infant formula identify the specific change and include side-by-side, detailed schematic

diagrams comparing the new processing to the previous processing (including processing times and temperatures). The comment asserted that, to date, a narrative description of the change has been acceptable and that preparing side-by-side, detailed schematic diagrams of current and new systems would require substantial amounts of additional administrative support, and no deficiencies in the narrative description have been identified.

(Response) FDA disagrees with this comment. The Agency regards the two elements in proposed § 106.120(b)(4) (narrative description of change and side-by-side diagrams) as complementary parts that will ensure that the Agency receives a complete picture of the proposed processing change(s). A narrative can provide a succinct means of describing the specific parameters of the change; however, it is not always apparent where the change fits into the overall processing operation, and detailed side-by-side diagrams of the current and new processing systems provide an efficient way to present the entire picture of the infant formula production and draw attention to the specific change or changes. These diagrams assist the Agency in understanding the manufacturer's processing methods, the interrelationship of various parts of the manufacturing process, and the sequence of production events for an infant formula. At least some infant formula manufacturers understand the value of these comparative diagrams because they are routinely included in their infant formula submissions to complement the narrative description of a processing change. Because manufacturers must update their schematic processing diagrams as part of their CGMP procedures, it seems unlikely that requiring comparative diagrams in new infant formula submissions will be an undue burden. For these reasons, FDA is not persuaded to revise proposed § 106.120(b)(4) in response to these comments. Section 106.120(b)(4) is included in this interim final rule as proposed, with the exception of minor editorial changes.

c. *Assurance for quality factors (Proposed § 106.120(b)(5)).*

In 1996, FDA proposed to implement section 412(d)(1)(C) of the FD&C Act through proposed § 106.120(b)(5). Proposed § 106.120(b)(5) would have required a new infant formula submission to include assurances that the infant formula would not be marketed unless the formula met the quality factor requirements of section 412(b)(1) of the FD&C Act and the nutrient content requirements of section 412(i) of the FD&C Act. Proposed § 106.120(b)(5)(i) provided that the assurances relating to quality factor requirements would be satisfied by a submission complying with proposed § 106.121, and proposed § 106.120(b)(5)(ii) provided that assurances relating to nutrient content would be satisfied by a statement that the formula would not be marketed unless it met the nutrient requirements of § 107.100, as demonstrated by required quality control testing.

FDA received no comments on proposed § 106.120(b)(5) that are not addressed elsewhere in the interim final rule.

d. *Assurance for processing infant formulas (Proposed § 106.120(b)(6)).*

The 1996 proposal (proposed § 106.120(b)(6)) would have required that the new infant formula submission include assurance that the processing of the infant formula complies with section 412(b)(2) of the FD&C Act. Proposed § 106.120(b)(6)(ii) would have required that the submission include the basis on which each ingredient meets the requirements of § 106.40(a) and that any claim that an ingredient is GRAS be supported by citation to the Agency's regulations or by an explanation of the basis for the general recognition of safety of the ingredient in infant formula. The proposed rule would have required that such explanation include a list of published studies and a copy of those publications that provide the basis for the general recognition of safety for the use of the ingredient in infant formula.

FDA received several comments on proposed § 106.120(b)(6)(ii) and responds to those comments directly below.

(Comment 324) One comment requested that FDA delete proposed § 106.120(b)(6)(ii), challenging FDA's legal interpretation that this information could be required as a part of the new infant formula submission. The comment asserted that in promulgating the Infant Formula Act, Congress intended that the law be used to ensure that the manufacturer produce formulas that meet the Infant Formula Act nutrient composition requirements and that are not contaminated with substances or organisms that might adulterate the product.

(Response) FDA disagrees with this comment. The authority for the requirement in proposed § 106.120(b)(6)(ii) is derived from section 412(d)(1)(D) of the FD&C Act. The submission requirement under section 412(d)(1)(D) of the FD&C Act requires infant formula manufacturers to provide assurances that the formula complies with section 412(b)(2) of the FD&C Act. The FD&C Act is silent as to the specific assurances that must be made to demonstrate that the formula is processed in accordance with section 412(b)(2) of the FD&C Act. Because the FD&C Act is silent, the Agency may issue a regulation to fill any gaps in the statutory requirement to provide assurances that an infant formula is processed in accordance with section 412(b)(2) of the FD&C Act so long as the regulation is not "arbitrary, capricious, or manifestly contrary to statute." *See Chevron,* 467 U.S. at 844.

Section 412(b)(2) of the FD&C Act requires FDA to issue regulations to establish good manufacturing practices and quality control procedures that the Secretary (and by delegation, FDA) determines are necessary to assure that the formula provides nutrients in accordance with section 412(i) of the FD&C Act and is manufactured in a manner designed to prevent adulteration of the formula.

Compliance with proposed § 106.120(b)(6)(ii) will provide assurance that an infant formula is manufactured in a manner designed to prevent adulteration. As noted previously in this document, under the CGMP requirement in § 106.40(a) of the interim final rule, the only substances that may be used in infant formula are those that are GRAS for such use, are used in accordance with a food additive regulation, or are authorized by a prior sanction. The failure to use a lawful ingredient in the manufacture of an infant formula would adulterate such formula. To provide adequate assurance that this CGMP requirement has been met, FDA is including a requirement that a new infant formula submission include the basis on which each ingredient satisfies the requirements of § 106.40(a) of the interim final rule.

Infant formula manufacturers may add ingredients to infant formula that are not "nutrients" as defined in this interim final rule. In fact, many infant formulas on the market today contain ingredients that are not required by section 412(i) of the FD&C Act, such as DHA, ARA, and microorganisms referred to as "probiotics." In circumstances in which the manufacturer has determined that an ingredient is GRAS for use in infant formula, there is no requirement under the FD&C Act that FDA review such ingredient prior to its use in infant formula and before the formula is marketed for use by infants. For certain ingredients (e.g., oligosaccharides, oils containing long chain polyunsaturated fatty acids, or intentionally added microorganisms), identification of the

ingredient and the supplier is necessary in order for FDA to determine whether the manufacturer is using the ingredient that has gone through the food additive petition or GRAS notification process.

FDA considers the provision in proposed § 106.120(b)(6)(ii) to be important in ensuring public health protection to this particularly vulnerable population. The submission of the information required under § 106.120(b)(6)(ii) of the interim final rule will provide FDA with the information it needs to ensure that a manufacturer has considered the basis for why each ingredient used in its infant formula is lawful prior to using an ingredient in the manufacture of infant formula. By identifying the basis on which each ingredient is believed to lawful, assurances are provided under section 412(d)(1)(D) of the FD&C Act that the use of each ingredient is safe and suitable under the applicable food safety provisions of the FD&C Act, as required by § 106.40(a) of the interim final rule. Therefore, FDA is not removing § 106.120(b)(6)(ii) in response to this comment, and § 106.120(b)(6)(ii) is included in this interim final rule as proposed.

(Comment 325) One comment objected to this provision arguing that Congress did not intend to give FDA premarket approval authority over infant formula or, in this case, over food ingredients employed in formula. The comment further asserted that 21 CFR 170.30 does not mandate that the information the manufacturer is relying upon be submitted to the Agency or be formally acknowledged or listed as GRAS.

(Response) As is explained previously in this document, Congress gave FDA the authority to establish regulations to assure that formula is manufactured in a manner designed to prevent its adulteration, and also gave FDA the authority to require that manufacturers provide assurance that the formula is manufactured in such a manner. To the extent that the comment asserts that proposed § 106.120(b)(6)(ii) establishes premarket approval authority for infant formula or its ingredients, FDA disagrees. Proposed § 106.120(b)(6)(ii) would simply require that the manufacturer provide the basis for why each ingredient it uses in its infant formula is safe under the FD&C Act. The review of ingredient safety under section 409 of the FD&C Act is separate and distinct from the responsibility for a manufacturer, as part of CGMP, to ensure that the formula satisfies the requirements designed to prevent the use of an unlawful ingredient in infant formula. Therefore, FDA is making no changes to § 106.120(b)(6)(ii) in the interim final rule in response to this comment.

(Comment 326) One comment stated that in many or most cases, manufacturers will, in the interest of reducing regulatory uncertainties, find it in their own self-interest to submit such information required under proposed § 106.120(b)(6)(ii); however, such submissions should remain voluntary. Therefore, the comment concluded, the manufacturer should be able to market the infant formula without submitting this information, because it is the manufacturer's responsibility to ensure the safety and suitability of its individual infant formula products.

(Response) As discussed previously in this document, FDA disagrees that proposed § 106.120(b)(6)(ii) should be removed from the interim final rule, and thus, does not believe that the provisions in proposed § 106.120(b)(6)(ii) should be voluntary. Additionally, FDA notes that ensuring that the ingredients used to produce an infant formula are lawful under the separate applicable statutory and regulatory requirements of the FD&C Act is still the responsibility of the infant formula manufacturer. Nothing in this interim final rule relieves a manufacturer of its obligations to evaluate the safety of the ingredients in its infant formula products and to comply with other substantive provisions of the FD&C Act relating to the safety of ingredients in infant formula.

(Comment 327) Several comments requested that proposed § 106.120(b)(6)(ii) be revised to apply only to "newly added" ingredients and not to ingredients already found in infant formula. The comments asserted that absent this change, information in infant formula submissions would be redundant and that this information is unnecessary for ingredients previously used and submitted by a manufacturer.

(Response) FDA disagrees with this comment. Only substances that are GRAS for use in infant formula, used in accordance with a food additive regulation, or authorized by a prior sanction may be used in infant formula. FDA notes that it may be appropriate in certain situations for a formula manufacturer to reference a previous submission in order to provide the basis that an ingredient in the formula satisfies § 106.40(a) of the interim final rule.

3. Products for Export Only (Proposed § 106.120(c))

Proposed § 106.120(c) would have required that for products intended for export only, a new infant formula submission include, in lieu of the information required under proposed § 106.120(b), a statement that the infant formula complies with section 801(e) of the FD&C Act (i.e., that the formula meets the specifications of the foreign purchaser, does not conflict with the laws of the country to which it is intended for export, is labeled on the outside of the shipping package to indicate that it is intended for export only, and will not be sold or offered for sale in domestic commerce).

(Comment 328) One comment objected to proposed § 106.120(c) asserting that is it redundant with section 801(e) of the FD&C Act.

(Response) FDA disagrees that proposed § 106.120(c) is redundant with section 801(e) of the FD&C Act. Proposed § 106.120(c) would permit a manufacturer of new infant formula for export only to submit, in lieu of the information required under § 106.120(b), a statement that the infant formula meets the specifications of the foreign purchaser, does not conflict with the laws of the country to which it is intended for export, is labeled on the outside of the shipping package to indicate that it is intended for export only, and will not be sold or offered for sale in domestic commerce. A manufacturer of a new infant formula, including a new infant formula for export only, is required by section 412(c)(1)(B) of the FD&C Act to make a submission to FDA 90 days prior to going to market. The failure to provide the notice required by section 412(c) of the FD&C Act (which includes a submission to FDA required by section 412(d) of the FD&C Act) is a prohibited act under section 301(s) of the FD&C Act (21 U.S.C. 321(s)). Section 412(d)(1) of the FD&C Act requires all persons who introduce a new infant formula, or deliver such formula for introduction into interstate commerce, to make a submission. Such persons include those who manufacture a new infant formula for export only; although such formula is exported, the formula is still introduced or delivered for introduction into "interstate commerce," as such term is defined in section 201(b) of the FD&C Act (21 U.S.C. 321(b)). There is no exception for an infant formula for export only in either section 412 or section 801 of the FD&C Act to the submission requirements of section 412 of the FD&C Act. Thus, a manufacturer that produces an infant formula for export only is required to make a submission under section 412(c) of the FD&C Act. Consequently, FDA is not removing from the interim final rule the

submission requirement for these formulas.

However, FDA is revising § 106.120(c) in the interim final rule to clarify the assurances that must be provided under section 412(d) of the FD&C Act for a new infant formula for export only.

Proposed § 106.120(c) would allow a manufacturer of a new infant formula for export only to make a submission to FDA that includes a statement that the formula meets the specifications of the foreign purchaser, does not conflict with the laws of the foreign country to which it is intended for export, is labeled on the outside of the package that it is intended for export only, and that it will not be sold in domestic commerce.

A product intended for export shall not be deemed to be adulterated or misbranded under the provisions of the FD&C Act if such product satisfies the criteria in section 801(e) of the FD&C Act. Thus, an infant formula for export only would not need to show that its formula meets those requirements of section 412 of the FD&C Act that, if not met, would cause the product to be adulterated, provided that the manufacturer shows that the formula meets the requirements in section 801(e) of the FD&C Act. This fact means that the submission of a manufacturer of a new infant formula intended for export could differ from the submission of a manufacturer of a new infant formula that is to be sold in domestic commerce, specifically with respect to the requirements of section 412(d)(1)(C) of the FD&C Act (quality factor and nutrient requirements) and section 412(d)(1)(D) of the FD&C Act (CGMP and quality control requirements), both of which establish conditions under which a formula would be adulterated under section 412(a) of the FD&C Act. In lieu of providing assurances that the processing of the formula complies with applicable quality factor, nutrient, and CGMP requirements under section 412(d)(1)(C) and (d)(1)(D) of the FD&C Act, a manufacturer of an infant formula for export only would notify FDA in its submission that its formula satisfies the criteria in section 801(e) of the FD&C Act.

Importantly, however, the submission requirements in sections 412(d)(1)(A) and (d)(1)(B) of the FD&C Act do not relate to adulteration: Section 412(d)(1)(A) of the FD&C Act requires a submission that includes the quantitative formulation of the formula and section 412(d)(1)(B) of the FD&C Act requires a description of any reformulation or change in the processing of the formula. The proposed rule would not have required a manufacturer of a new infant formula for export only to submit the quantitative formulation of the new infant formula or a description of any reformulation or change in the processing of the formula.

Because proposed § 106.120(c) would allow a manufacturer of a new infant formula for export only to make an alternate submission to fulfill all of the submission requirements, including the requirements not specifically related to adulteration of the infant formula, FDA is revising § 106.120(c) to permit a manufacturer of a new infant formula for export only to make an alternative submission to satisfy only those requirements of section 412(d)(1) of the FD&C Act that are related to adulteration. Thus, under the interim final rule, a manufacturer of a new infant formula for export only is required, as it would be for an infant formula for domestic commerce, to submit the quantitative formulation of the formula and a description of any reformulation or change in the processing of such formula. By providing such information, the manufacturer of a new infant formula for export only will be complying with the submission requirement in section 412(d)(1) of the FD&C Act in a way that is consistent with the requirements in section 801(e) of the FD&C Act. Additionally, as explained previously in this document, FDA is revising proposed § 106.120(c) to require that, as a condition of making the alternate submission under § 106.120(c), a manufacturer of a new infant formula for export only certify that the manufacturer has adequate controls in place to ensure that such formula is actually exported.

(Comment 329) Several comments claimed that manufacturers of infant formulas for export only should not be required to make the submission under proposed § 106.120(c) 90 days before marketing, asserting that there may be situations in which 90 days advance notice could cause hardship to a manufacturer. One comment proposed that a manufacturer could notify FDA of its intent to export infant formula prior to commercial distribution, arguing that this process should not cause FDA hardship because the relative simplicity of the export notification and the brevity of the review typically required.

(Response) As explained in response to the previous comment, every manufacturer of a new infant formula, including a new infant formula for export only, is required by section 412(c)(1)(B) of the FD&C Act to make a submission to FDA 90 days prior to going to market. Thus, FDA is making no changes to § 106.120(c) in response to this comment.

(Comment 330) One comment suggested that proposed § 106.120(c) should be revised to state "For products for export only and in compliance with Section 801(e) of the FD&C Act, the information under paragraph (b) of this section is not required and need not be submitted." The comment asserted that FDA's proposed requirements under proposed § 106.120(c) are adequately covered under the FDA Export Reform Enhancement Act and its implementing regulations (21 CFR part 1).

(Response) FDA disagrees with this comment. The requirements in this interim final rule are separate and distinct from those issued under other authorities related to requirements in 21 CFR part 1. Section 106.120(c) of the interim final rule specifies what must be included in a submission required under section 412(d)(1) of the FD&C Act for a new infant formula intended for export only. As explained previously in this document, this submission is required for all new infant formulas, including a new infant formula for export only. The requirements in 21 CFR Part 1, Subpart E, do not implement section 412 of the FD&C Act. Therefore, FDA is not making the changes requested in this comment.

4. Administrative Procedures for Handling Notifications (Proposed § 106.120(d), (e), and (f))

Proposed § 106.120 includes several subparts that address the administrative aspects of new infant formula submissions. Specifically, proposed § 106.120(d) would have provided that a submission would not constitute notice under section 412 of the FD&C Act unless the submission complied fully with proposed § 106.120(b) and was readily understandable, and that FDA would notify the submitter of the inadequacy of a submission. Proposed § 106.120(e) would have provided that FDA would acknowledge receipt of an adequate submission and the date of receipt ("the filing date"), and restated the prohibition against marketing the new infant formula until 90 days after the filing date. Finally, proposed § 106.120(f) would have stipulated that if a manufacturer supplemented a new infant formula submission, FDA would determine whether it was a substantive amendment, and if so, the Agency would assign a new filing date and notify the submitter of the new date.

(Comment 331) One comment suggested that proposed § 106.120(d) be revised to require FDA to notify the submitter within 10 working days if the submission is not complete because it

does not meet the requirements of sections 412(c) and (d) of the FD&C Act. The comment asserted that manufacturers filing a new infant formula submission need certainty for planning purposes, that an Agency notice of inadequacy received well into the 90-day review period can be seriously disruptive, and that a submission should receive immediate review for completeness.

(Response) FDA agrees that a new infant formula submission should be checked immediately for completeness to ensure that it contains all elements required under proposed § 106.120(b). A submission lacking any element required under proposed § 106.120(b) will not be filed, and the Agency will notify the submitter in a timely manner that the submission is not complete. FDA would anticipate that this completeness determination could generally be made within 10 business days. However, given the constraints and conflicting demands on Agency resources at various times, the Agency declines to add this time restriction to § 106.120(d).

(Comment 332) One comment suggested that FDA delete the last sentence of proposed § 106.120(e), which would have stipulated that a manufacturer not market a new infant formula until 90 days after the filing date, because this language is not found in the FD&C Act and is unnecessarily restrictive. The comment noted that the 1996 proposal stated (61 FR 36154 at 36198) that the purpose of the 90 day notice is to provide the Agency sufficient time to examine the submission and decide whether there is any basis for concern about the marketing of the formula, and, the comment contended, a manufacturer should not be prohibited from marketing a formula if, prior to the 90th day, the Agency has made its determination that there is no concern.

(Response) FDA disagrees with this comment. Section 412(c)(1)(B) of the FD&C Act states that no "person shall introduce or deliver for introduction into interstate commerce any new infant formula unless . . . such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c)(1)." [8] The clear import of this provision is that a new infant formula shall not be marketed until the passage of the 90 day period. The statute does not require FDA to communicate with the submitter, and the Agency, in its discretion, has chosen not to impose such an obligation on itself because the requirement is unnecessary and would be burdensome. In these circumstances, a manufacturer will know that marketing of its new infant formula is lawful only with the passing of the 90th day. FDA notes that, if the Agency's review of a new infant formula submission uncovers deficiencies such that the new infant formula in question would not be in compliance with the FD&C Act, the Agency intends to notify the manufacturer of such deficiencies prior to the 90th day. Accordingly, FDA declines to revise proposed § 106.120(e) in response to this comment.

(Comment 333) One comment suggested that proposed § 106.120(e) be revised to state that if a new infant formula submission is complete and includes all information required by § 106.120(b), FDA will acknowledge its receipt and notify the submitter of the date of the receipt. The comment expresses concern that the Agency might wish to delay the starting date of the 90 day period when the notification is complete but questions or disagreement remain with respect to the content. The comment contended that the marketing of an infant formula should not be deferred while the Agency takes issue with minor elements of the notification and that when FDA receives a notification that supplies information in accordance with § 106.120, the 90-day clock must begin to run.

(Response) FDA stated in the response to Comment 331 that, in the Agency's view, there is a distinction between verifying a submission's completeness versus determining that the information satisfies the requirements of the law and the relevant regulations by providing the necessary assurances and demonstrating that the new infant formula will not be adulterated under the FD&C Act. The latter determination requires complete and careful examination of the submitted material by Agency personnel with the necessary expertise, such as manufacturing specialists, statisticians, microbiologists, nutritionists, food technologists, and medical officers. In contrast, once the Agency determines that a new infant formula submission is complete in that it purports to address all the requirements of § 106.120(b) of the interim final rule, FDA intends to provide the submitter with a prompt acknowledgement letter, and the 90 day period will begin as of the date that the Agency receives a complete submission.

In response to the foregoing comments, FDA is revising proposed § 106.120(e) to clarify the distinction between an FDA notification that a submission is complete and a notification that the submission does not provide the assurances required by section 412(d)(1) of the FD&C Act and the regulations implementing those assurances.

(Comment 334) One comment suggested that, in proposed § 106.120(f), instead of referring to the "manufacturer" providing additional information in support of a new infant formula submission and FDA notifying the manufacturer of the new filing date, it would be more appropriate to refer to the "submitter" providing additional information and FDA notifying the "submitter" of the new filing date.

(Response) FDA disagrees with the suggestion of this comment and, for the reasons discussed below, is retaining the term "manufacturer" in § 106.120(f) of the interim final rule. For purposes of uniformity, the Agency is also revising §§ 106.120(d), 106.130(c), and 106.140(c) by replacing the term "submitter" with "manufacturer."

The manufacturer of an infant formula is ultimately responsible for ensuring that that its formula products are lawful. In the case of a new infant formula, FDA must be provided with all the information required in a new infant formula submission at least 90 days before the new formula is distributed in commerce. Thus, the formula manufacturer must ensure that such information is provided in a timely fashion to FDA. Also, section 412(c) of the FD&C Act refers to "person" and requires such person to notify FDA of all establishments at which such person intends to manufacture the new infant formula. Thus, "person," as used in section 412(c) of the FD&C Act, refers to the manufacturer of the infant formula.

FDA recognizes that a manufacturer may contract with other entities to execute certain aspects of formula production. However, the manufacturer will be held responsible for the information submitted to FDA, whether submitted by the manufacturer or another person who submits it on behalf of the manufacturer, and FDA will notify the manufacturer, under § 106.120(f) of the interim final rule, whether the Agency considers additional information submitted by any person on behalf of the manufacturer in support of the submission to constitute a substantive amendment resulting in a new filing date.

For these reasons, FDA is retaining the term "manufacturer" in § 106.120(f) of the interim final rule, and, for consistency reasons, is amending §§ 106.120(d), 106.130(c), and

[8] FDA has previously stated the view that this reference to subsection (c)(1) is a drafting error and is understood to refer to subsection (d)(1)). (61 FR 36154 at 36195, footnote 6).

106.140(c) in the interim final rule by replacing the term "submitter" with the term "manufacturer."

(Comment 335) One comment requested that FDA revise proposed § 106.120(f) by adding a time period (5 working days) within which FDA would acknowledge receipt of additional information provided to support a new infant formula submission that is a substantive amendment to the submission, asserting that FDA must be bound by some reasonable time requirements so that manufacturers can plan appropriately.

(Response) FDA agrees that the Agency should promptly notify a manufacturer of receipt of a supplement to a new infant formula submission, but the Agency declines to add a 5-day time limit to proposed § 106.120(f) within which to acknowledge such receipt. FDA would anticipate that this acknowledgement could generally be made within 5 business days. However, given the constraints and conflicting demands on Agency resources at various times, the Agency declines to add this time restriction or any other specific time restriction to § 106.120(f) in the interim final rule. There is no assurance that FDA can meet this 5-day time limit given constraints that may be placed on Agency resources at various times.

5. Submissions for Exempt Infant Formulas (Proposed § 106.120(g))

On its own initiative, FDA is adding § 106.120(g) to the interim final rule to clarify that the submission requirements for exempt infant formulas are codified in 21 CFR 107.50. Section 106.120(g) of the interim final rule states: "Submissions relating to exempt infant formulas are subject to the provisions of § 107.50 of this chapter." The regulations in 21 CFR 107.50 pertaining to exempt infant formula were finalized in 1985 (50 FR 48183) prior to the 1986 amendments. As explained in the 1996 proposal, the Agency will address in a separate rulemaking the effect of the 1986 amendments on the exempt infant formula regulations and exempt infant formulas (61 FR 36154 at 36201–36202). Until FDA publishes such rulemaking, exempt infant formula submissions are subject to § 107.50.

D. Quality Factor Submissions for Infant Formulas (Proposed § 106.121)

To provide assurance that an infant formula meets the quality factor requirements set forth in subpart E, the proposed rule described in detail the requirements for a quality factor submission in proposed § 106.121. The Agency received comments on these proposed requirements, and responds below. Although much of the substance of proposed § 106.121 has been retained in the interim final rule, FDA notes that the numbering of the section has been revised.

1. General Comments

(Comment 336) One comment suggested that proposed § 106.121 be revised to clarify that the quality factor submission requirements of proposed § 106.121 only apply to "new infant formulas" as defined by these regulations.

(Response) FDA agrees with this comment. Under section 412(d)(1) of the FD&C Act, any infant formula subject to section 412(c) must make a submission to FDA. Each "new infant formula" is subject to section 412(c) of the FD&C Act. As such, FDA is making revisions to § 106.121 in the interim final rule to clarify that the submission requirements only apply to a "new infant formula." The Agency notes, however, that all infant formulas, whether new or "not new," are required to satisfy the applicable quality factor requirements of § 106.96 of the interim final rule.

(Comment 337) One comment recommended that § 106.121(a) be retained as proposed and that the remaining paragraphs in § 106.121 applying to the quality factor of normal physical growth (proposed § 106.121(b), (c), (d), and (f)) be deleted for the reasons identified in the comments objecting to establishment of "normal growth" as a quality factor. The comment's support for retention of proposed § 106.121(a), as well as its support for deletion of § 106.121(d), was contingent on FDA's acceptance of the comment's suggested changes to proposed § 106.120(b)(6)(i), (ii), and (iii). Another comment on proposed § 106.121 identified various changes to infant formula and suggested a decision-tree approach to determining the documentation that would be required for each such change to support nutritional adequacy. The comment concluded that FDA should provide information about presentation of clinical growth study data in an Agency guidance and not the final rule.

(Response) FDA disagrees with the comment that all information on the presentation of growth monitoring study data should be incorporated into an FDA guidance and not codified in § 106.121. The data and information required in a quality factor submission to assure normal physical growth (proposed § 106.121(b), (c), (d), and (f)) provide the basic factual information that is needed for the Agency's review of the growth monitoring study. Because these items are necessary to an adequate review of the study, they should not, and cannot, be described as optional elements of a submission. Therefore, FDA declines to delete proposed § 106.121(b), (c), (d), and (f), and these requirements are, with minor editorial changes, incorporated into the interim final rule recodified as § 106.121(a)(2), (a)(3), (a)(4), and (h) respectively. Proposed § 106.121(a) is recodified as § 106.121(a)(1) in the interim final rule, with minor editorial changes.

Additional comments were submitted for proposed § 106.121(b), (c), and (f) and are addressed below.

2. Submission of Growth Data (Proposed § 106.121(b))

Proposed § 106.121(b) would have required that a quality factor submission include certain data from the growth monitoring study. FDA received several comments that addressed the types of data that should be submitted to comply with proposed § 106.121(b).

(Comment 338) One comment objected to submitting data for individual subjects or a subgroup of individuals from a formula feeding group. This comment expressed concern that, because few infants will be at the lower or upper end of a particular growth parameter in a normal distribution, the characteristics of these individuals could erroneously be considered representative of a significant subgroup of the sample. The comment requested that FDA clarify that group statistics will provide the primary basis for the manufacturer's finding that normal physical growth has been attained and that the growth data for individual study infants will be considered as supportive data and only to demonstrate that there was no significant subgroup of the study group that experienced adverse effects.

(Response) FDA declines to implement the suggestion of this comment. Although the Agency intends to rely primarily on the group data of a growth monitoring study to demonstrate the safety, including the nutritional adequacy, of an infant formula, it has been the Agency's experience that the review of summary data may raise issues the resolution of which requires the consideration of individual or subgroup data. For example, by examining detailed data, FDA has been able to determine that there were no subgroups of the test population for whom the formula had adverse effects. Thus, providing individual subject data will facilitate FDA's review of the submission because the Agency will be able to review individual data promptly and resolve particular questions without

an intervening request to the manufacturer for additional data and information. This efficiency is especially important given the limited time (90 days) provided by the statute for the Agency's review of a new infant formula submission. Accordingly, FDA is not persuaded to revise the requirement of proposed § 106.121(b), and this provision is codified with minor editorial changes in the interim final rule as § 106.121(a)(2).

(Comment 339) One comment suggested that growth data be presented as plotted growth curves of the group means and that the Agency not require individual case report forms and data. The comment pointed out that including data on individual infants would add to the length of the submission and to the length of the FDA's review without providing a meaningful benefit to the public.

(Response) FDA disagrees with this comment. As noted previously in this document, the prompt availability of individual study results will support the efficiency of FDA's review of the growth study and the prompt resolution of issues identified by the Agency's review of the group study results. Growth curves reflecting group means only may be submitted but their submission is not an acceptable alternative for submission of individual data. Importantly, FDA notes that in terms of the form of individual study results, original records are not required but may be submitted. In addition to the requirement to submit data plotted on the 2009 CDC growth charts, manufacturers may submit such information in any easily understandable format, which includes spreadsheets, data tables, copies of investigators' original clinical study records, or case report forms with original data (for example, individual anthropometric data sheets). A submission form that contains the individual subject data in an accessible format will satisfy FDA's need for comprehensive information.

(Comment 340) One comment requested that the preamble acknowledge that the "records" contemplated by proposed § 106.121(b) need not be the investigator's original records, but could be records that contain the necessary information drawn from the investigator's original records.

(Response) As noted in the response to the preceding comment, to comply with § 106.121(a)(2) of the interim final rule, a manufacturer may submit the required information in any easily interpretable format. Original records are not required to, but may, be submitted to comply with § 106.121(a)(2) of the interim final rule.

(Comment 341) One comment on proposed § 106.121(b) disagreed with the requirement to submit the records that contain the information required by proposed § 106.97(a)(1)(ii).

(Response) As discussed previously in this document in section VIII.C, FDA is not finalizing the Agency's proposed recommendations for a clinical study protocol in the interim final rule. However, not issuing proposed § 106.97(a)(1)(ii) in the interim final rule does not change FDA's need to review the data and information that were covered by proposed § 106.121(b) to provide assurance that a new infant formula meets the quality factor requirement of normal physical growth. Thus, § 106.96(b) of the interim final rule identifies the data and other information that must be collected during a growth monitoring study. FDA's reasons for retaining these substantive requirements are discussed previously in this document in section VIII.C. Accordingly, the Agency is not revising proposed § 106.121(b) in response to this comment; the provision is recodified as § 106.121(a)(2) in the interim final rule with minor editorial changes.

3. Statistical Power Calculations (Proposed § 106.121(c)(2))

Proposed § 106.121(c)(2) would have required the quality factor submission to include the calculation of the statistical power of a study at its completion. FDA received several comments on this proposed requirement.

(Comment 342) One comment noted that a calculation of a study's statistical power is needed before a study is initiated and it is reasonable to expect from a study report that there was an *a priori* calculation of the study's power, the number of subjects to be recruited, and the number of subjects who actually completed the study. The comment asserted that a calculation of a study's power at its completion, as would have been required by proposed § 106.121(c)(2), is unnecessary and of unproven value and could be a confounding and burdensome calculation. Accordingly, the comment recommended that FDA not require inclusion of such a calculation in a quality factor submission.

(Response) FDA agrees with this comment to the extent that it asserts that the statistical power of a study should be calculated prior to study initiation to determine the number of subjects needed to answer the clinical question. It is both reasonable and reflects a sound scientific approach for a manufacturer to perform a prospective power calculation and include that calculation in a quality factor submission relating to the growth monitoring study. A prospective power calculation may be used to determine whether the study, as designed, will have sufficient statistical power to answer the question of whether a formula has the ability to satisfy the quality factor of normal physical growth. Thus, the interim final rule requires a manufacturer to calculate the statistical power of a growth monitoring study prior to its initiation and to submit that calculation to FDA in a new infant formula submission.

The proposed rule would have required the calculation of the statistical power of the growth monitoring study at its completion and the inclusion of the calculation in the quality factor submission. A prospective calculation of study power and sample size is based on predicted variance and expected dropout rates whereas a power calculation conducted at the end of a study uses actual values for the study size and drop-out rates. As explained in the 1996 proposal (61 FR 36154 at 36199), a study may not achieve the power predicted by the prospective power calculation if dropout rates or measurement errors are greater than anticipated. Thus, an end-of-study calculation can help determine whether the failure to detect a difference between formulas occurred because the clinical study lacked the statistical power to detect differences if such differences existed. Failure to detect real differences could result in an erroneous conclusion that a formula supports normal physical growth, when in fact, it does not. Although *post hoc* analyses are generally discouraged, a planned, post-study statistical power calculation is, in FDA's view, necessary to ensure that the study, as actually conducted, achieved the statistical power projected by the prospective statistical power analysis.

FDA disagrees that a post-study power calculation is confounding and burdensome. The data needed for these calculations are required to be collected during the growth monitoring study, and the calculations are straightforward and performed using standard statistical software packages. For these reasons, the Agency is not deleting proposed § 106.121(c)(2) in response to this comment.

Based on the foregoing comments, the interim final rule requires that the quality factor portion of a new infant formula submission include both a prospective and a retrospective power calculation. Thus, proposed

§ 106.121(c)(2) is included in this interim final rule as § 106.121(a)(3)(ii) and states "Calculations of the statistical power of the study before study initiation and at study completion."

4. Protein Quality (Proposed § 106.121(e))

Proposed § 106.121(e) would have required that the quality factor submission include the results of the PER study, consistent with proposed § 106.97(b). FDA received comments on this proposed requirement.

(Comment 343) One comment suggested that proposed § 106.121(e) be deleted and that the results of the PER be submitted to the Agency after the first production, and before the introduction into interstate commerce, of the new infant formula, as part of the verification submission required by proposed § 106.130. The comment further suggested that proposed § 106.130(b) be revised to require that the verification submission include an assurance that the bioassay for protein biological quality has commenced, and that the PER results will be provided to FDA within 10 working days of their receipt by the manufacturers or responsible party as a supplement to the verification submission.

The comment also asserted that if the use of new production equipment triggers the 90-day premarket notification requirement, a requirement to submit the PER testing in the 90-day premarket submission would accelerate the need to start testing by 5 months (2 months to conduct the PER test plus three months to be able to give the notification 90 days before marketing). This would delay the start-up with the new equipment by 5 months or require the manufacturer to convince FDA that the research production system was "close enough" to the full scale system so that the product of the former would be viewed as representative of the latter.

(Response) FDA is not persuaded by this comment to require the submission of PER bioassay results as part of the verification submission under § 106.130. Nor is the Agency persuaded to require that the verification submission only require an assurance that the bioassay for protein biological quality was commenced, and that the results will be forwarded to FDA within 10 working days of their receipt by the manufacturer.

Requiring the results of the PER bioassay to be submitted in a new infant formula submission is consistent with both the relevant law and sound science. As discussed previously in this document in section VIII.E, FDA has established biological quality of the protein as a quality factor for infant formula and has identified the PER bioassay (appropriately modified) as the requirement that must be met to provide assurance that this quality factor is satisfied. Section 412(d)(1) of the FD&C Act requires that a new infant formula submission contain assurances that the formula will not be marketed unless it satisfies the quality factors established under section 412(b)(1) of the FD&C Act. Indeed, in the 1996 proposal (61 FR 36154 at 36196), FDA tentatively concluded that it would be appropriate to require the assurance that the quality factors will be met by the submission of data under proposed § 106.120(b)(5)(i) and not as part of the verification submission so that the Agency has all the information relevant to the nutritional adequacy of the formula for a period of time sufficient to conduct a meaningful review. Further, as discussed previously in this document, it is appropriate that the biological quality of a formula's protein component be established by the manufacturer prior to initiation of a growth monitoring study to avoid exposing infants to a test formula for which the protein quality has not been confirmed. For these reasons, FDA concludes that it is appropriate to require that the results of the PER assay be submitted to the Agency as a part of the new infant formula submission made under § 106.120 of the interim final rule.

5. Certification Statement (Proposed § 106.121(f))

Proposed § 106.121(f) would have required that a new infant formula submission include a statement that certifies that the manufacturer has collected and considered all information on the ability of an infant formula to satisfy the quality factor requirements and that the manufacturer is unaware of other information or data that would show that the formula did not satisfy the quality factors requirements. FDA received one comment on this provision.

(Comment 344) One comment suggested a change to proposed § 106.121(f). The comment requested that FDA change "certifying" to "of assurance" to reflect the language of section 412(d)(1)(C) and (d)(1)(D) of the FD&C Act, which language refers to "assurances" and not "certifications."

(Response) FDA is not persuaded by this comment. The requirement that a manufacturer include this certification in a quality factor submission is a means of assuring FDA that the manufacturer has considered the totality of available information and is not aware of any information or data that would show that the formula does not meet quality factor requirements. Therefore, FDA declines to revise proposed § 106.121(f) in response to this comment. Accordingly, proposed § 106.121(f) is recodified as § 106.121(i) and is included in this interim final rule as proposed.

6. Satisfaction of an Exemption From Certain Quality Factor Requirements

As discussed in section VIII.D, FDA is including exemptions from the quality factor requirements in § 106.96(b) and (f) as part of this interim final rule (see § 106.96(c) and (g) of the interim final rule). A manufacturer may rely on an exemption, as applicable, in a new infant formula submission to provide assurances that the formula meets a quality factor requirement. Therefore, FDA is adding conforming changes to § 106.121 of the interim final rule to clarify the requirements pertaining to each of these exemptions. To the extent a manufacturer relies on an exemption in a new infant formula submission, the applicable requirement in § 106.121 of the interim final rule would provide the Agency with the data and information in such submission that the manufacturer relies on to demonstrate that the formula satisfies such exemption from the quality factor requirements.

E. Verification Submissions (Proposed § 106.130)

In 1996, FDA proposed to implement section 412(d)(2) of the FD&C Act by requiring that, after the first production, but before the introduction into interstate commerce, of a new infant formula, a manufacturer verify in a written submission to FDA that the formula complies with the FD&C Act and is not adulterated. The proposal would have required that the verification submission summarize test results and records demonstrating that the formula satisfies the requirements of section 412(b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i) of the FD&C Act.

FDA received several comments on the proposed verification requirement.

1. Scope of Verification Submission Requirement

(Comment 345) One comment requested that FDA clarify that infant formulas for export only are not required to submit a verification submission under proposed § 106.130.

(Response) FDA agrees that clarification about how a manufacturer of a new infant formula for export only can comply with § 106.130 is needed.

The verification that must be submitted to FDA under section 412(d)(2) of the FD&C Act relates to whether the formula is adulterated under section 412(a) of the FD&C Act. As discussed previously in this document, a manufacturer of a new infant formula for export only may choose to comply with § 106.120(c) of the interim final rule instead of § 106.120(b) of the interim final rule. If a manufacturer complies with § 106.120(c) of the interim final rule, there would not be a need for the manufacturer of a product that is for export only to submit a verification concerning compliance with requirements that relate to the adulteration provisions. FDA would consider the submission under § 106.120(c) of the interim final rule to satisfy the verification submission requirement in § 106.130 of the interim final rule for such formula. Therefore, FDA has revised § 106.130(a) in the interim final rule as follows: "A manufacturer shall, after the first production and before the introduction into interstate commerce of a new infant formula (except for a new infant formula that is for export only for which a submission is received in compliance with § 106.120(c)), verify in a written submission to FDA at the address given in § 106.110(a) that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated."

2. Identification Number (Proposed § 106.130(b)(1))

(Comment 346) One comment suggested that proposed § 106.130(b)(1), which would have required that the verification submission include the identification number assigned by the Agency to the new infant formula submission, should be qualified to state that the verification submission must include this identification number, if available. The comment asserted that oftentimes, the identification number might not have been assigned or be available.

(Response) FDA does not agree with this comment. Including the FDA-assigned identification number in the verification submission is a simple and reasonable means to permit FDA to link a verification submission with the corresponding new infant formula submission. As part of its standard procedures, FDA assigns an identification number to each new infant formula submission received and includes this number in a letter to the manufacturer acknowledging the new infant formula submission. An infant formula manufacturer that does not receive, in a timely way, an Agency acknowledgement letter in response to an infant formula submission should contact FDA during the 90-day review period. Accordingly, FDA is not revising proposed § 106.130(b)(1), and this provision is included in this interim final rule as proposed.

3. Verified Formula Matches Notified Formula (Proposed § 106.130(b)(2))

(Comment 347) One comment requested that proposed § 106.130(b)(2), which would have required that the verification submission include a statement that the infant formula to be introduced into interstate commerce is the same as the infant formula that was the subject of the new infant formula submission and for which the manufacturer provided assurances in accordance with the requirements of § 106.120, should be modified to allow that if the infant formula is not the same, the verification submission must include an explanation of how the infant formula is different and why this difference does not affect the quality factor requirements. In support of this change, the comment stated that occasionally, a minor change may be made to an infant formula between the time a 90-day submission is made and the first production occurs and that, although these changes are not expected to have an adverse impact on nutrient levels or nutrient availability, the two formulations would not be "the same." Thus, the comment asserted that the verification submission should provide a mechanism to record and explain these situations.

(Response) FDA disagrees with this comment. Section 412(d)(2) of the FD&C Act requires that an infant formula manufacturer submit a written verification to FDA after the first production of an infant formula (the "first-produced" formula) subject to section 412(c) of the FD&C Act and before such formula is introduced into interstate commerce. Therefore, the FD&C Act requires that the infant formula addressed by the verification submission be the same formula that is the subject of the new infant formula submission (the "notified formula") previously submitted under section 412(c) of the FD&C Act. In the proposed rule (61 FR 36154 at 36200), FDA tentatively concluded that if a manufacturer can make the statement that would have been required by proposed § 106.130(b)(2), it means that the quality factor assurances that the manufacturer provided in the new infant formula submission continue to be relevant and applicable to the product and thus, no additional information would need to be included in the verification submission to demonstrate compliance with sections 412(b)(1) and 412(b)(2)(A) of the FD&C Act. FDA concludes that the statement in proposed § 106.130(b)(2) is necessary and is in lieu of additional test results or records demonstrating compliance of the "first-produced" formula with these sections of the FD&C Act. If the "first-produced" formula differs from the "notified formula" in ways that would constitute a major change or if the "first-produced" formula has otherwise been changed such that previous submission on quality factor requirements and ingredient safety is no longer relevant, the manufacturer could not truthfully make the statement in proposed § 106.130(b)(2). Thus, a manufacturer must evaluate whether it can make the statement in § 106.130(b)(2) in light of any changes to the formula.

For these reasons, FDA is not revising proposed § 106.130(b)(2) in response to this comment, and this provision is included in this interim final rule as proposed.

4. Certification Statement (Proposed § 106.130(b)(4))

(Comment 348) One comment suggested that proposed § 106.130(b)(4) be revised to delete the proposed requirement that a verification submission contain a certification that the manufacturer has established current good manufacturing practices, including quality control procedures and in-process controls such as testing, designed to prevent adulteration of this formula in accordance with subparts B and C of part 106, and instead, to require that the verification submission contain assurance that the manufacturer has done so. The comment states that the suggested use of "assurance" was based on the provisions of the Infant Formula Act relating to verification that refer specifically to "assurance" as opposed to certification.

(Response) FDA is not persuaded by this comment. First, although FDA agrees that the word "assurance" is used in section 412 of the FD&C Act, the comment does not describe the difference, material or otherwise, between a suggested requirement that a manufacturer provide "assurance" and the proposed requirement that a manufacturer provide a "certification" as to compliance with CGMP requirements. Absent such a distinction, FDA sees no reason to change the language proposed. The certification is the means by which a manufacturer provides the assurance required under section 412(d) of the FD&C Act.

Second, the proposed certification requirement is reasonable. FDA is

responsible for reviewing the manufacturer's submission to ensure the infant formula complies with the FD&C Act, and the Agency must be satisfied that a manufacturer has, in accordance with subparts B and C of part 106, established current good manufacturing practices, including quality control procedures, in-process controls, and testing required by CGMP that is designed to prevent adulteration of the formula. Section 412(d)(2) of the FD&C Act requires that after the first production of a new infant formula and before its introduction into interstate commerce, the formula manufacturer submit written verification summarizing test results and records demonstrating that the formula complies with the requirements of section 412(b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i) of the FD&C Act. As the Agency tentatively concluded in the proposed rule, and concludes in this interim final rule, additional test results or records demonstrating compliance with section 412(b)(2)(B)(i), (b)(3)(A), and (b)(3)(C) of the FD&C Act are unnecessary because such testing is subsumed under § 106.130(b)(3) of the interim final rule in the summary of test results for the level of each nutrient required by § 107.100. Section 106.130(b)(3) of the interim final rule includes the test results for the level of nutrients required by 412(i) of the FD&C Act. Further, the Agency concludes that it would be unnecessary to require submission of the records demonstrating compliance with section 412(b)(1) of the FD&C Act because the records demonstrating compliance with quality factors would have been submitted as part of the submission under section 412(c) and (d)(1)(C) of the FD&C Act. The certification requirement in proposed § 106.130(b)(4) is a means to satisfy the statutory provision that a manufacturer summarize test results and records to demonstrate compliance with sections 412(b)(2)(A) and (b)(2)(B)(iii) of the FD&C Act. Such records would be available for inspection by FDA. This requirement will be a strong incentive to a manufacturer to confirm that the test results and records that demonstrate compliance with section 412(b)(2)(A) and (b)(2)(B)(iii) of the FD&C Act are complete based on the manufacturer's established procedures. For these reasons, FDA is not revising proposed § 106.130(b)(4) in response to this comment, and the provision is included in this interim final rule as proposed.

5. Administrative Procedures for Handling Verification Submissions (Proposed § 106.130(c))

(Comment 349) One comment suggested modifying proposed § 106.130(c), which states that a submission will not constitute written verification under section 412(d)(2) of the FD&C Act when any data prescribed by proposed § 106.130(b) are lacking or are not set forth so as to be readily understood and that, in such circumstances, the Agency will notify the submitter that the verification is not adequate. The comment suggested that this proposed provision be revised to state that the Agency will notify the submitter within 5 working days that the notice is not complete and asserted that without such rapid notice, a manufacturer will not be able to market its product with assurance that FDA found the submission acceptable. The comment also recommended that the FDA develop a form for verifications that will help in FDA's review of the sufficiency of these submissions.

(Response) FDA disagrees with this comment. Although the Agency fully intends to notify a manufacturer of the inadequacy of a verification submission as promptly as possible, it is not reasonable for FDA to commit to a specific time frame for such notice where it is not compelled by statute and where, in some cases, competing priorities or diminished resources may affect the Agency's ability to respond.

Similarly, it is not necessary for the Agency to develop a form for verification notifications because proposed § 106.130 specifies the information required in such a notification, and the Agency's review will focus on those requirements. Development and clearance of such a form would require Agency resources, and the comment did not specifically identify the efficiencies or other benefits from the use of the suggested form that would be expected to offset these development and clearance costs. Accordingly, FDA is not revising proposed § 106.130(c) in response to this comment, and, with minor editorial changes, the provision is included in this interim final rule as proposed.

F. Submission Concerning a Change in Infant Formula That May Adulterate the Product (Proposed § 106.140)

In 1996, the Agency proposed submission requirements to implement section 412(d)(3) of the FD&C Act by issuing proposed § 106.140. Proposed § 106.140 would have required that when a manufacturer makes a change in the formulation or processing of an infant formula that may affect whether the formula is adulterated under section 412(a) of the FD&C Act, the manufacturer shall, before the first processing of such formula, make a submission to FDA at the address given in proposed § 106.110(a).

The Agency received several comments on proposed § 106.140, and responds below.

(Comment 350) One comment expressed concern that infant formula manufacturers may be reluctant to make minor changes in packaging materials because they may think that these changes would require additional stability testing of their formulas and additional notifications to FDA under proposed § 106.140. The comment requested that FDA clarify that an infant formula manufacturer does not need to conduct special stability testing or make a filing with FDA, in accordance with proposed § 106.140, when a packaging change is made that clearly will not affect potential migration of packaging components to the formula or the integrity of the packaging.

(Response) FDA is not persuaded to make changes to the codified based on this comment. Section 412(d)(3) of the FD&C Act provides that a manufacturer is to make the determination as to whether a change in the processing may affect whether the formula is adulterated. FDA considers that a change in packaging constitutes a change in processing for purposes of section 412(d)(3) of the FD&C Act. Therefore, if a manufacturer determines that a packaging change may affect whether a formula may be adulterated, a notification to FDA, in accordance with § 106.140 of the interim final rule, is required.

Stability testing is governed by § 106.91(b)(2) of the interim final rule. Under that provision, a manufacturer is responsible for ensuring that an infant formula satisfies the nutrient requirements of the FD&C Act throughout the shelf life of the product. When a manufacturer makes a packaging change for a specific formula, the manufacturer must determine whether that change requires the manufacturer to conduct additional stability testing to ensure that the infant formula will contain the required nutrients throughout the shelf life of the product. Moreover, the definition of "major change" includes a situation where there is a fundamental change in the type of packaging used and such a change would make the formula a "new" infant formula for which a submission would be required under section 412(c) of the FD&C Act.

Accordingly, FDA is not revising proposed § 106.140 in response to this comment, and the provision is included in this interim final rule as proposed.

1. "Before First Processing" (BFP) Submissions (Proposed § 106.140(a))

(Comment 351) One comment suggested that proposed § 106.140(a) be revised to state that when a manufacturer makes a change in the formulation or processing of a formula that the manufacturer or responsible party determines may affect whether the formula is adulterated under section 412(a) of the FD&C Act, the manufacturer shall, before the first processing of such formula, make a submission to the FDA. The comment asserted that this revision would clarify what constitutes a "minor change" versus a "major change."

(Response) Elsewhere in this preamble, FDA has declined to define "minor change" and reaffirms that decision now in response to this comment. FDA notes that this comment suggests changes to proposed § 106.140 that the comment believes would clarify what constitutes a "major" or "minor" change. However, the definition of "major change" is addressed in section 412(c) of the FD&C Act and is defined in § 106.3 of the interim final rule. The comment does not explain the utility or necessity of defining "minor change," and such a definition is not necessary. Also, unlike "major change," for which there are regulatory consequences (for example, filing a submission under § 106.120), there are no regulatory consequence identified in the law or by the comment for a change that would be a "minor change." For this reason, FDA declines to define "minor change" in response to this comment.

(Comment 352) Another comment stated that under current practice, infant formula manufacturers currently evaluate all changes to formulation or processing of their infant formulas and if the manufacturer determines the change may affect the nutrient content of the formulation, the manufacturer notifies FDA. The comment asserted that this requirement will increase the number of these submissions and require additional personnel if a manufacturer is required to notify FDA when any of the changes listed as examples of "notifiable changes" in the preamble to the proposed rule occurs.

(Response) Proposed § 106.140 was designed to implement section 412(d)(3) of the FD&C Act, which requires that a manufacturer make a submission to FDA before the first processing of a formula when the manufacturer determines that a change in formulation or in the processing of an infant formula may affect whether a formula is adulterated under section 412(a) of the FD&C Act; the submission is required by section 412(d)(3) of the FD&C Act to conform to the requirements in section 412(d)(1) of the FD&C Act. A change that constitutes a "major change" within the meaning of § 106.3 of the interim final rule is not the type of change that requires notification under § 106.140 because a "major change" makes a formula a "new infant formula" and under section 412(c)(1) of the FD&C Act, the manufacturer of a "new infant formula" must notify FDA of the change in accordance with section 412(c)(1) of the FD&C Act and § 106.120 of the interim final rule. The comment cited examples of changes that FDA identified in the preamble to the proposed rule that could affect whether a formula is adulterated and stated that increased submissions and a need for additional personnel would be required, but the comment did not explain why such examples are inconsistent with section 412(d)(3) of the FD&C Act. The examples FDA provided are of the type that the Agency considers appropriate for submission under section 412(d)(3) of the FD&C Act and proposed § 106.140(a).

Based on the foregoing, FDA is not revising proposed § 106.140(a) in response to these comments, and proposed § 106.140(a) is included in this interim final rule, with minor editorial changes, as proposed.

No comments were received requesting modification of proposed § 106.140(b)(1). Thus, proposed § 106.140(b)(1) is included in this interim final rule as proposed.

2. Steps To Ensure That Formula Will Not Be Adulterated (Proposed § 106.140(b)(2))

(Comment 353) One comment suggested that proposed § 106.140(b)(2), which requires that the submission explain why the change in formulation or processing may affect whether the formula is adulterated, also would require that the submission explain the steps that will be taken to ensure that the formula will not be introduced into interstate commerce unless it is not adulterated. The comment asserted that this suggested requirement will enable FDA to receive a more complete explanation of the change.

(Response) FDA agrees with this comment. The Agency believes that requiring a manufacturer to consider how it will resolve a question of whether the formula is actually adulterated and to provide that explanation to FDA will help to ensure that no adulterated formula will enter distribution. Accordingly, FDA is revising § 106.140(b)(2) in response to this comment to require that the submission explain the steps that will be taken to ensure that, before the formula is introduced into interstate commerce, the formula will not be adulterated.

3. Administrative Procedures (Proposed § 106.140(c))

(Comment 354) One comment suggested that proposed § 106.140(c), which provides that the Agency will notify the submitter if a notice is not adequate because it does not meet the requirements of section 412(d)(3) of the FD&C Act, be revised to state that FDA will promptly acknowledge receipt and notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the FD&C Act. The comment asserted that FDA should be required to notify manufacturers within 1 week, or some other reasonable period of time, if a submission is not adequate and that otherwise, a manufacturer will not be able to market its product with assurance that FDA found the submission to be adequate.

(Response) FDA disagrees with this comment. The Agency's current practice is to acknowledge the receipt of a new infant formula submission. However, FDA declines to revise the interim final rule to require such acknowledgment because future changes in Agency resources and program priorities may make the current practice of acknowledgement not feasible. Also, a manufacturer may make independent arrangements to confirm FDA's receipt of its submission, such as by sending the submission via U.S. mail with return receipt service.

Similarly, although the Agency intends to notify a manufacturer of the inadequacy of a submission made under § 106.140 of the interim final rule as promptly as possible, it is not reasonable for FDA to commit to a specific time frame for such notice where such timing is not compelled by statute and where, in some cases, competing priorities or diminished resources may affect the Agency's ability to respond. Thus, FDA is not persuaded to revise proposed § 106.140(c) in response to this comment, and this provision is included in this interim final rule, with minor editorial changes, as proposed.

4. Infant Formulas Intended for Export Only

(Comment 355) One comment requested clarification as to whether

infant formulas intended only for export must make the submission concerning a change in infant formula that may adulterate the product. The comment suggested that § 106.140 include a paragraph (d) that would state that the requirements of § 106.140 do not apply to any infant formula product legally exported under section 801(e) of the FD&C Act.

(Response) The Agency is not revising § 106.140 in response to this comment. Notification under § 106.140 is only necessary when the manufacturer makes a change to the formula that affects whether the formula may be adulterated under section 412(a) of the FD&C Act. As explained previously in this document, an infant formula intended for export is not deemed to be adulterated under the FD&C Act, including under section 412(a) of the FD&C Act, if it is in compliance with section 801(e) of the FD&C Act. FDA would not consider an infant formula intended for export that is in compliance with § 106.120(c) of the interim final rule and section 801(e) of the FD&C Act to be adulterated under section 412(a) of the FD&C Act. Therefore, an infant formula for export only that is in compliance with § 106.120(c) of the interim final rule and section 801(e) of the FD&C Act would not be required to make any notification under § 106.140 of the interim final rule.

However, the Agency advises that if a manufacturer makes a change to its infant formula for export only that constitutes a "major change" within the meaning of § 106.3 of the interim final rule, the manufacturer would be required to make a 90-day new infant formula submission under § 106.120 of the interim final rule. As stated in earlier in this preamble, a new infant formula that is for export only shall comply with §§ 106.110 and 106.120 of the interim final rule. Importantly, a manufacturer of a new infant formula for export only may make an alternative submission under § 106.120(c) of the interim final rule for the submission requirements that relate to whether the new infant formula is adulterated under section 412(a) of the FD&C Act. However, if a manufacturer of a new infant formula for export only elects to make a new infant formula submission under § 106.120(b) of the interim final rule, the manufacturer would be required to submit a verification submission under § 106.130 of the interim final rule and the submission concerning a change in infant formula that may adulterate the product, if the formula was changed under § 106.140 of the interim final rule. When a manufacturer makes a new infant formula submission under § 106.120(b) of the interim final rule, the Agency reviews the application using the requirements in the FD&C Act and FDA's implementing regulations to determine whether the formula meets these requirements and thus, is eligible to be marketed in the United States. If a manufacturer elects to have its formula reviewed as a formula to be marketed in the United States, it must make all of the relevant submissions required by the FD&C Act for such formulas.

G. Notification of an Adulterated or Misbranded Infant Formula (Proposed § 106.150)

In the 1996 proposal, FDA proposed to recodify § 106.120(b) in subpart G and to designate the recodified provision as § 106.150. The proposed recodification included several minor editorial changes to the text of current § 106.120(b).

The Agency received several comments on this proposed recodification, and responds below.

(Comment 356) One comment suggested a modification of proposed § 106.150(a)(2), which would have required that a manufacturer promptly notify FDA if an infant formula that the manufacturer has processed and that has left the manufacturer's control may be adulterated or misbranded. The comment suggested adding the following: "In the case of 'adulteration' based on a failure to follow CGMP, the failure must be of such a nature as to reasonably call into question the suitability of the formula. Notification shall not be required for minor or technical misbranding." In support of this suggestion, the comment asserted that a violation of the infant formula CGMP, no matter how minor or inconsequential, will constitute a "technical adulteration or misbranding" of the product, that formula manufacturers are of the only members of the food industry compelled to notify FDA when a distributed product is or may be "adulterated" or "misbranded," and thus, it is critical to weigh each proposed regulation for the consequences of a finding of "adulteration" or "misbranding" to ensure that such regulations are appropriate. The comment concluded that only adulteration of public health significance and only significant or actionable misbranding should trigger notification.

(Response) FDA disagrees that with this comment. Proposed § 106.150, and its predecessor, current § 106.120(b), implement section 412(e)(1)(B) of the FD&C Act. This statutory provision requires a formula manufacturer to notify the Secretary (and by delegation, FDA) when the manufacturer has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer may not provide the nutrients required by section 412(i) of the FD&C Act or "may be otherwise adulterated or misbranded." Section 412(e)(1) of the FD&C Act provides that the Secretary (and by delegation, FDA), and not the manufacturer, shall determine whether the released infant formula presents a risk to human health. Thus, it is incumbent upon the FDA to evaluate the public health risk that may be associated with an adulterated or misbranded infant formula, and the modification requested in this comment would be inconsistent with the governing statutory provision.

In addition, FDA disagrees that § 106.150(a) should be modified so that notification of adulteration based on a failure to follow CGMP need only be made if the failure to follow CGMP reasonably calls into question the suitability of the formula. A failure to follow CGMP indicates that a manufacturer's process is not under appropriate control, and thus, a manufacturer should promptly and fully address such failure following discovery. Only if FDA is aware of the finding of a breach of infant formula CGMP can the Agency appropriately monitor the manufacturer and ensure that further problems do not develop. Moreover, as noted elsewhere in this preamble, safety considerations are of unique importance with infant formula because such formula is intended to be the sole source of nutrition for infants during the early period of significant development and growth. Therefore, it is incumbent upon the Agency to evaluate the public health risks that may be associated with an adulterated or misbranded infant formula.

FDA recognizes that some infant formula CGMP failures may not have public health consequences. However, the Agency must be made aware of all formulas that have left the control of the manufacturer that may be adulterated or misbranded so that FDA can discharge its obligation under section 412(e)(1) of the FD&C Act. Accordingly, FDA declines to modify proposed § 106.150 in response to this comment.

The Agency is, however, modifying § 106.150(b) to update the contact information for submission of a notification of an adulterated or misbranded infant formula. Thus, § 106.150(b) of the interim final rule

requires, in part, that the manufacturer "shall promptly send written confirmation of the notification to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement (HFS–605), Recall Coordinator, 5100 Paint Branch Parkway, College Park, MD 20740, and to the appropriate FDA district office."

H. Incorporation by Reference

Certain material is incorporated by reference in the interim final rule with the approval of the Director of the Federal Register. For purposes of clarity and ease of reference, FDA has gathered in a single place in the interim final rule (§ 106.160) a list of the material that is incorporated by reference and information about how these materials may be obtained from their source.

XI. Conforming Amendments to Part 107

In 1996, FDA proposed revisions to the regulations in part 107 to reflect the changes made by the 1986 amendments and the regulations that FDA was proposing to adopt in part 106. The Agency also proposed certain editorial changes. FDA received no comments on the proposed revisions to part 107.

As explained elsewhere in this preamble, the interim final rule revises certain proposed provisions in part 106, which revisions were made in response to comments or for other reasons. Also, due to the passage of time, additional technical changes to part 107 are necessary to update Agency addresses and telephone numbers. Accordingly, as included in this interim final rule, part 107 reflects the revisions proposed in 1996 modified by additional technical changes and changes required for consistency with the provisions of part 106.

XII. Environmental Impact

The Agency has determined under 21 CFR 25.30(j) and 25.32(n) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIII. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. Regulatory Impact Analysis for Interim Final Rule

FDA has examined the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this interim final rule (Ref. 92) which is available at *http://www.regulations.gov* (enter Docket No. FDA–1995–N–0036). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available at *http://www.regulations.gov*. We believe that the interim final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to our analysis, we believe that the interim final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this interim final rule to result in any 1-year expenditure that would meet or exceed this amount.

The analyses that we have performed to examine the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 92).

We included a *Summary of the Economic Analysis of the Proposed Rule* in the RIA (Ref. 92. We received comments on our analysis of the impacts presented in those sections, and the RIA (Ref. 92) contains our responses to those comments.

XV. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). A description of these provisions with estimates of the annual reporting, recordkeeping, and third-party disclosure burden are included in the RIA in section IV, entitled "Paperwork Reduction Act of 1995" (Ref. 92). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

In the July 9, 1996, proposed rule, FDA included an analysis of the information collection provisions of the proposal under the PRA and requested comments on four questions relevant to that analysis (61 FR at 36205–36206). Subsequently, in 2003, the Agency reopened the comment period to update comments and to receive any new information on all issues, including on the PRA analysis (68 FR 22341). In response to these requests, FDA received no comments specifically referring to the Agency's 1996 PRA analysis or otherwise referring to the PRA. FDA did receive comments on the substantive provisions of the proposed rule, including comments on the proposed recordkeeping and other provisions of the proposal that would result in information collections. FDA has summarized and responded to these comments in the RIA (Ref. 92).

As noted, the 1996 proposal included a PRA analysis. FDA is re-estimating the burden of this interim final rule using current burden analysis methodology. The Agency invites comments on new issues relating to the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of

FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

In compliance with the PRA, FDA has submitted the information collection provisions of this interim final rule to OMB for review. Prior to the effective date of this interim final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XVI. Comments

The requirements in this interim final rule will be in effect on July 10, 2014. FDA invites the public to comment on this interim final rule. Comments submitted in response to this interim final rule should be limited to those that present new issues or new information. Comments previously submitted to the Division of Dockets Management have been considered and addressed in this interim final rule and should not be resubmitted.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this interim final rule. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XVII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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List of Subjects

21 CFR Part 106

Food grades and standards, Infants and children, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 106 and 107 are amended as follows:

■ 1. Revise part 106 to read as follows:

PART 106—INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS

Subpart A—General Provisions

Sec.

Subpart B—Current Good Manufacturing Practice

Subpart C—Quality Control Procedures

Subpart D—Conduct of Audits

Subpart E—Quality Factors for Infant Formulas

Subpart F—Records and Reports

Subpart G—Registration, Submission, and Notification Requirements

Authority: 21 U.S.C. 321, 342, 350a, 371.

Subpart A—General Provisions

§ 106.1 Status and applicability of the regulations in part 106.

(a) The criteria set forth in subparts B, C, and D of this part prescribe the steps that manufacturers shall take under section 412(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)(2) and (b)(3)) in processing infant formula. If the processing of the formula does not comply with any regulation in subparts B, C, or D of this part, the formula will be deemed to be adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria set forth in subpart E of this part prescribe the requirements for quality factors that infant formula shall meet under section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the formula fails to comply with any regulation in subpart E of this part, it will be deemed to be adulterated under section 412(a)(2) of the Federal Food, Drug, and Cosmetic Act.

(c) The criteria set forth in subpart F of this part prescribe records requirements for quality factors under section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act and for good manufacturing practices and quality control procedures, including distribution and audit records, under section 412(b)(2). If an infant formula manufacturer fails to comply with the quality factor record requirements in subpart F of this part with respect to an infant formula, the formula will be deemed to be adulterated under section 412(a)(2) of the Federal Food, Drug, and Cosmetic Act. If an infant formula manufacturer fails to comply with the good manufacturing practices or quality control procedures record requirements in subpart F of this part with respect to an infant formula, the infant formula will be deemed to be adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act. The criteria set forth in subpart F of this part also implement record retention requirements under section 412(b)(4) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart F of this part is a violation of section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)).

(d) The criteria set forth in subpart G of this part describe, in part, certain good manufacturing practices, quality control procedures, and quality factor records requirements under section 412(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act. If an infant formula manufacturer fails to comply with such records requirements with respect to an infant formula, the infant formula will be deemed to be adulterated under section 412(a)(2) or (a)(3) of the Federal Food, Drug, and Cosmetic Act, as applicable. The criteria set forth in subpart G of this part also describe the circumstances in which an infant formula manufacturer is required to register with, submit to, or notify the Food and Drug Administration, and the content of a registration, submission, or notification, under section 412(c), (d), and (e) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart G of this part is a violation of section 301(s) of the Federal Food, Drug, and Cosmetic Act.

§ 106.3 Definitions.

The definitions in this section and the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) shall apply to infant formula requirements in 21 CFR parts 106 and 107 of this chapter.

Eligible infant formula means an infant formula that could have been or was lawfully distributed in the United States on May 12, 2014.

Final product stage means the point in the manufacturing process, before distribution of an infant formula, at which the infant formula is homogeneous and is not subject to further degradation due to processing.

Indicator nutrient means a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and uniform distribution of a premix or other substance of which the indicator nutrient is a part.

Infant means a person not more than 12 months of age.

Infant formula means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

In-process production aggregate means a combination of ingredients at any point in the manufacturing process before packaging.

Major change in an infant formula means any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any

change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer. Examples of infant formulas deemed to differ fundamentally in processing or in composition include:

(1) Any infant formula produced by a manufacturer who is entering the U.S. market;

(2) Any infant formula powder processed and distributed by a manufacturer who previously only produced liquids (or vice versa);

(3) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience;

(4) Any infant formula manufactured on a new processing line or in a new plant;

(5) Any infant formula manufactured containing a new constituent not listed in section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)), such as taurine or L-carnitine;

(6) Any infant formula processed by a manufacturer on new equipment that utilizes a new technology or principle (e.g., from terminal sterilization to aseptic processing); or

(7) An infant formula for which there has been a fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

Manufacturer means a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution. The term "manufacturer" does not include a person who prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.

Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance.

New infant formula means:

(1) An infant formula manufactured by a person that has not previously manufactured an infant formula, and

(2) An infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer, or which has not previously been the subject of a submission under section 412(c) of the Federal Food, Drug, and Cosmetic Act for the U.S. market.

Nutrient means any vitamin, mineral, or other substance or ingredient that is required in accordance with the "Nutrients" table set out in section 412(i)(1) of the Federal Food, Drug, and Cosmetic Act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or that has been identified as essential for infants by the Food and Drug Administration through a **Federal Register** publication.

Nutrient premix means a combination of ingredients containing two or more nutrients received from a supplier or prepared by an infant formula manufacturer.

Production aggregate means a quantity of product, or, in the case of an infant formula produced by continuous process, a specific identified amount produced in a unit of time, that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a master manufacturing order.

Production unit means a specific quantity of an infant formula produced during a single cycle of manufacture that has uniform composition, character, and quality, within specified limits.

Production unit number or production aggregate number means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a production aggregate or a production unit of infant formula can be determined.

Quality factors means those factors necessary to demonstrate the bioavailability and safety of the infant formula, as prepared for market and when fed as the sole source of nutrition, including the bioavailability of individual nutrients in the formula, to ensure the healthy growth of infants.

Representative sample means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

Shall is used to state mandatory requirements.

Subpart B—Current Good Manufacturing Practice

§ 106.5 Current good manufacturing practice.

(a) The regulations set forth in this subpart define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under § 107.100 of this chapter and is manufactured in a manner designed to prevent its adulteration. A liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container is also subject to the regulations in part 113 of this chapter, and an infant formula that is an acidified food, as defined in § 114.3(b) of this chapter, is also subject to the regulations in part 114 of this chapter.

(b) The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)); the failure to comply with any regulation in part 113 of this chapter in the manufacture, processing, packing, or holding of a liquid infant formula shall render such infant formula adulterated under section 412(a)(3); and the failure to comply with any regulation in part 114 of this chapter in the manufacture, processing, packing, or holding of an infant formula that is an acidified food shall render such infant formula adulterated under section 412(a)(3).

§ 106.6 Production and in-process control system.

(a) A manufacturer shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.

(b) The production and in-process control system shall be set out in a written plan or set of procedures that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, a manufacturer shall:

(1) Establish specifications to be met;

(2) Monitor the production and in-process control point, step, or stage;

(3) Establish a corrective action plan for use when a specification established in accordance with paragraph (c)(1) of this section is not met;

(4) Review the results of the monitoring required by paragraph (c)(2) of this section, and review and evaluate the public health significance of any deviation from specifications that have been established in accordance with paragraph (c)(1) of this section. For any specification established in accordance with paragraph (c)(1) of this section that a manufacturer fails to meet, an individual qualified by education, training, or experience shall conduct a documented review and shall make a material disposition decision to reject the affected article, to reprocess or otherwise recondition the affected article, or to approve and release the article for use or distribution; and

(5) Establish recordkeeping procedures, in accordance with § 106.100(e)(3), that ensure that compliance with the requirements of this section is documented.

(d) Any article that fails to meet a specification established in accordance with paragraph (c)(1) of this section shall be controlled under a quarantine system designed to prevent its use pending the completion of a documented review and material disposition decision.

§ 106.10 Controls to prevent adulteration by workers.

(a) A manufacturer shall employ sufficient personnel, qualified by education, training, or experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that the operations are correctly and fully performed.

(b) Personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces shall practice good personal hygiene to protect the infant formula against contamination. Good personal hygiene includes:

(1) Wearing clean outer garments and, as necessary, protective apparel such as head, face, hand, and arm coverings; and

(2) Washing hands thoroughly in a hand washing facility with soap and running water at a suitable temperature before starting work, after each absence from the work station, and at any other time when the hands may become soiled or contaminated.

(c) Any person who reports that he or she has, or appears by medical examination or supervisory observation to have, an illness, open lesion (including boils, sores, or infected wounds), or any other source of microbial contamination that creates a reasonable possibility that the safety of an infant formula may be adversely affected, shall be excluded from direct contact with ingredients, containers, closures, in-process materials, equipment, utensils, and infant formula product until the condition is corrected or determined by competent medical personnel not to jeopardize the safety of the infant formula.

§ 106.20 Controls to prevent adulteration caused by facilities.

(a) Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations.

(b) Separate areas or another system of separation, such as a computerized inventory control, a written card system, or an automated system of segregation, shall be used for holding raw materials, in-process materials, and final infant formula product at the following times:

(1) Pending release for use in infant formula production or pending release of the final product;

(2) After rejection for use in, or as, infant formula; and

(3) After release for use in infant formula production or after release of the final product.

(c) Lighting shall allow easy identification of raw materials, packaging, labeling, in-process materials, and finished products that have been released for use in infant formula production and shall permit the easy reading of instruments and controls necessary in processing, packaging, and laboratory analysis. Any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product shall be protected to prevent glass from contaminating the product in the event of breakage.

(d) A manufacturer shall provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate the infant formula; and shall minimize the potential for contamination of raw materials, in-process materials, final product infant formula, packing materials, and infant formula-contact surfaces, through the use of appropriate measures, which may include the use of air filtration.

(e) All rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents shall be stored and used in a manner that protects against contamination of infant formula.

(f) Potable water used in the manufacture of infant formula shall meet the standards prescribed in the Environmental Protection Agency's (EPA's) Primary Drinking Water regulations in 40 CFR part 141, except that the water used in infant formula manufacturing shall not be fluoridated or shall be defluoridated to a level as low as possible prior to use.

(1) The water shall be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula.

(2) A manufacturer shall test representative samples of the potable water drawn at a point in the system at which the water is in the same condition that it will be when it is used in infant formula manufacturing.

(3) A manufacturer shall conduct the tests required by paragraph (f)(2) of this section with sufficient frequency to ensure that the water meets the EPA's Primary Drinking Water Regulations but shall not conduct these tests less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants.

(4) A manufacturer shall make and retain records, in accordance with § 106.100(f)(1), of the frequency and results of testing of the water used in the production of infant formula.

(g) There shall be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for infant formula manufacturing.

(h) Only culinary steam shall be used at all direct infant formula product contact points. Culinary steam shall be in compliance with the 3–A Sanitary Standards, No. 60903, which is incorporated by reference at § 106.160. Boiler water additives in the steam shall be used in accordance with § 173.310 of this chapter.

(i) Each infant formula manufacturing site shall provide its employees with readily accessible toilet facilities and hand washing facilities that include hot and cold water, soap or detergent, single-service towels or air dryers in toilet facilities. These facilities shall be maintained in good repair and in a sanitary condition at all times. These facilities shall provide for proper disposal of the sewage. Doors to the

toilet facility shall not open into areas where infant formula ingredients, containers, or closures are stored, or where infant formula is processed or stored.

§ 106.30 Controls to prevent adulteration caused by equipment or utensils.

(a) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are of appropriate design and are installed to facilitate their intended function and their cleaning and maintenance.

(b) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. A manufacturer shall ensure that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and that all surfaces that contact ingredients, in-process materials, or infant formula are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source. All sanitizing agents used on such equipment and utensils that are regulated as pesticide chemicals under 21 U.S.C. 346a(a) shall comply with the Environmental Protection Agency's regulations established under such section, and all other such sanitizers shall comply with all applicable Food and Drug Administration laws and regulations.

(c) A manufacturer shall ensure that any substance, such as a lubricant or a coolant, that is required for operation of infant formula manufacturing equipment and which would render the infant formula adulterated if such substance were to come in contact with the formula, does not come in contact with formula ingredients, containers, closures, in-process materials, or with infant formula product during the manufacture of an infant formula.

(d) A manufacturer shall ensure that each instrument used for measuring, regulating, or controlling mixing time and speed, temperature, pressure, moisture, water activity, or other parameter at any point, step, or stage where control is necessary to prevent adulteration of an infant formula during processing is accurate, easily read, properly maintained, and present in sufficient number for its intended use.

(1) The instruments and controls shall be calibrated against a known reference standard at the time of or before first use and thereafter at routine intervals, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument or control. The known reference standard shall be certified for accuracy at the intervals specified in writing by the manufacturer of the instrument or control, or at routine intervals otherwise deemed necessary to ensure the accuracy of the instrument or control. A manufacturer shall make and retain records of the calibration activities in accordance with § 106.100(f)(2).

(2) Instruments and controls that cannot be adjusted to agree with the reference standard shall be repaired or replaced.

(3) If calibration of an instrument shows a failure to meet a specification for a point where control is deemed necessary to prevent adulteration of infant formula product, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, shall be made, in accordance with § 106.100(f)(2).

(e) The following provisions apply to thermal processing and cold storage of infant formulas:

(1) Equipment and procedures for thermal processing of infant formula packaged in hermetically sealed containers shall conform to the requirements in 21 CFR parts 108 and 113.

(2)(i) Except as provided in paragraph (e)(2)(ii) of this section, a manufacturer shall maintain all areas of cold storage at a temperature of 40 °F (4.4 °C) or below.

(ii) A manufacturer may maintain a cold storage area for an in-process infant formula or for a final infant formula at a temperature not to exceed 45 °F (7.2 °C) for a defined period of time provided that the manufacturer has scientific data and other information to demonstrate that:

(A) Compliance with paragraph (e)(2)(i) of this section would have an adverse effect on the quality of the in-process or the final infant formula through, e.g., destabilization or loss of homogeneity; and

(B) The time and temperature conditions of such storage are sufficient to ensure that there is no significant growth of microorganisms of public health significance during the period of storage of the in-process or final infant formula product.

(3)(i) Cold storage compartments and thermal processing equipment shall be equipped with easily readable, accurate temperature-indicating devices.

(ii) A manufacturer shall ensure that the temperature of each cold storage compartment is maintained by:

(A) Monitoring the temperature of the cold storage compartment on a temperature-indicating device and recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained;

(B) Equipping the cold storage compartment with one or more temperature-recording devices that will reflect, on a continuing basis, the true temperature, within the compartment;

(C) Equipping the cold storage compartment with a high temperature alarm that has been validated to function properly and recording the temperature in a record with such frequency as is necessary to ensure that temperature control is maintained; or

(D) Equipping the cold storage compartment with a maximum-indicating thermometer that has been validated to function properly and recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained.

(iii) A manufacturer shall, in accordance with § 106.100(f)(3), make and retain records of the temperatures recorded in compliance with § 106.30(e)(3)(ii).

(4) When a manufacturer uses a temperature-recording device for a cold storage compartment, such device shall not read lower than the reference temperature-indicating device.

(5) A manufacturer shall monitor the temperature in thermal processing equipment at points where temperature control is necessary to prevent adulteration. Such monitoring shall be at such frequency as is required by regulation or is necessary to ensure that temperature control is maintained.

(f) A manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula.

(1) An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed.

(2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with § 106.100(f)(4).

(g) A manufacturer shall ensure that compressed air or other gases that are mechanically introduced into infant formula, that are used to clean any equipment, or that come into contact

with any other surface that contacts ingredients, in-process materials, or infant formula product are treated in such a way that their use will not contaminate the infant formula with unlawful or other chemical, physical, or microbiological contaminants. When compressed gases are used at product filling machines to replace air removed from the headspace of containers, a manufacturer shall install, as close as practical to the end of the gas line that feeds gas into the space, a filter capable of retaining particles 0.5 micrometer or smaller.

§ 106.35 Controls to prevent adulteration due to automatic (mechanical or electronic) equipment.

(a) For the purposes of this section:

(1) "Hardware" means all automatic equipment, including mechanical and electronic equipment (such as computers), that is used in production or quality control of infant formula.

(2) "Software" means any programs, procedures, rules, and associated documentation used in the operation of a system.

(3) "System" means a collection of components (including software and hardware) organized to accomplish a specific function or set of functions in a specified environment.

(4) "Validation" means establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics.

(b) All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.

(1) A manufacturer shall ensure that hardware that is capable of being calibrated is routinely calibrated according to written procedures, and that all hardware is routinely inspected and checked according to written procedures.

(2) A manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula to ensure that the infant formula is not adulterated. The degree and frequency of input/output verification shall be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system.

(3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.

(4) A manufacturer shall ensure that any system that is modified is revalidated following the modification and prior to the release for distribution of any infant formula manufactured using the modified system. All modifications to software shall be made by a designated individual and shall be checked by the infant formula manufacturer to ensure that infant formula that is produced or analyzed using the modified software complies with this subpart and with subpart C of this part.

(c) A manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning mechanical or electronic equipment.

§ 106.40 Controls to prevent adulteration caused by ingredients, containers, and closures.

(a) The only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, a substance is used in accordance with the Agency's food additive regulations, is generally recognized as safe (GRAS) for such use, or is authorized by a prior sanction.

(b) Infant formula containers and closures shall not be reactive or absorptive so as to affect the safety of the infant formula. The following substances may be used as packaging material that comes in contact with an infant formula:

(1) A food additive that is the subject of a regulation issued under section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)) and is used consistent with the conditions of use of that regulation;

(2) A food contact substance that is the subject of an effective notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act and is used consistent with the conditions of use in that notification;

(3) A substance that is exempt from regulation as a food additive under § 170.39 of this chapter and its use conforms to the use identified in the exemption letter;

(4) A substance that is generally recognized as safe for use in or on infant formula or for use in infant formula packaging;

(5) A substance the use of which is authorized by a prior sanction from the Food and Drug Administration or from the U.S. Department of Agriculture; and

(6) A substance that is not a food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) because the substance is not reasonably expected to become a component of food or otherwise affect the characteristics of food.

(c) Ingredients, containers, and closures used in the manufacture of infant formula shall be identified with a lot number to be used in recording their disposition.

(d) A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use.

(e) Ingredients, containers, and closures shall be stored in separate areas or separated by a system of segregation, such as a computerized inventory control, a written card system, or an automated system of segregation, clearly designated for materials pending release for use; materials released for use; or materials rejected for use in infant formula production.

(1) Any lot of an ingredient, a container, or a closure that does not meet the manufacturer's specifications shall be quarantined under a system designed to prevent its use in the manufacture of infant formula until an individual qualified by education, training, or experience has conducted a documented review, has determined whether such failure could result in an adulterated infant formula, and has made and documented a material disposition decision to reject the ingredient, container, closure, or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, closure, or the affected infant formula; or to approve and release the ingredient, container, closure, or the affected infant formula for use.

(2) Any ingredient, container, or closure that has been reprocessed or otherwise reconditioned shall be the subject of a documented review and

material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use.

(3) A manufacturer shall not reprocess or otherwise recondition an ingredient, container, or closure rejected because it is contaminated with microorganisms of public health significance or other contaminants, such as heavy metals.

(f) If an ingredient, container, or closure that complies with a manufacturer's specifications, or that has been released for use following a material review and disposition decision, is subsequently exposed to air, heat, or other conditions that may adversely affect it, or if a manufacturer reasonably believes that an ingredient, container, or closure that complies with a manufacturer's specifications, or that has been released for use following a material review and disposition decision, has been exposed to air, heat, or other conditions that may adversely affect it, the ingredient, container, or closure shall be quarantined under a system designed to prevent its use in the manufacture of infant formula until an individual qualified by education, training, or experience has conducted a documented review and has made and documented a material disposition decision to reject the ingredient, container, or closure; to reprocess or otherwise recondition the ingredient, container, or closure; or to approve and release the ingredient, container, or closure for use.

(1) Any ingredient, container, or closure that is reprocessed or otherwise reconditioned shall be retested or reexamined and be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether the ingredient, container, or closure should be rejected, further reprocessed or otherwise further reconditioned, or approved and released for use.

(2) Any rejected ingredient, container, or closure shall be clearly identified as having been rejected for use in infant formula manufacturing or processing operations and shall be controlled under a quarantine system designed to prevent its use in infant formula manufacturing or processing operations.

(3) Any ingredient, container, or closure that has not been manufactured, packaged, labeled, or held under conditions to prevent adulteration under section 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) shall not be approved and released for use.

(g) A manufacturer shall make and retain records, in accordance with § 106.100(f)(6), on the ingredients, containers, and closures used in the manufacture of infant formula.

§ 106.50 Controls to prevent adulteration during manufacturing.

(a) A manufacturer shall prepare and follow a written master manufacturing order that establishes controls and procedures for the production of an infant formula.

(1) The manufacturer shall make and retain records, in accordance with § 106.100(e), that include complete information relating to the production and control of the production aggregate. An individual qualified by education, training, or experience shall conduct an investigation of any deviations from the master manufacturing order and document any corrective action taken.

(2) Changes made to the master manufacturing order shall be drafted, reviewed, and approved by a responsible official and include an evaluation of the effect of the change on the nutrient content and the suitability of the formula for infants.

(b) A manufacturer shall establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order is examined by one person and checked by a second person or system. This checking shall ensure that the correct ingredient is added during the manufacturing process, that the ingredient has been released for use in infant formula, and that the correct weight or measure of the ingredient is added to the production unit.

(c) A manufacturer shall establish a system of identification for the contents of all compounding and storage containers, processing lines, and major equipment used during the manufacture of a production aggregate of an infant formula. The system shall permit the identification of the processing stage and the unique identification number for the particular production unit or production aggregate of infant formula.

(d) A manufacturer shall establish controls to ensure that the nutrient levels required by § 107.100 of this chapter are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants. Such controls shall include:

(1) The mixing time; the speed, temperature, and flow rate of product; and other critical parameters necessary to ensure the addition of required ingredients to, and the homogeneity of, the formula;

(2) The spray-drying process for powdered infant formula, including the filtering of the intake air before heating, to prevent microbial and other contamination;

(3) The removal of air from the finished product to ensure that nutrient deterioration does not occur;

(4) Ensuring that each container of finished product is properly sealed. Such controls shall involve use of established procedures, specifications, and intervals of examination that are designed by qualified individuals and are sufficient to:

(i) Detect visible closure or seal defects, and

(ii) Determine closure strength through destructive testing. A manufacturer of a liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container shall perform such closure integrity testing in accordance with § 113.60(a) of this chapter.

(e) A manufacturer shall establish controls that ensure that the equipment used at points where control is deemed necessary to prevent adulteration is monitored, so that personnel will be alerted to malfunctions.

(f) A manufacturer shall establish controls for in-process material as follows:

(1) For any specification established in accordance with § 106.6(c)(1) that a manufacturer fails to meet for in-process material, an individual qualified by education, training, or experience shall conduct a documented review and shall make a material disposition decision to reject the affected in-process material, to reprocess or otherwise recondition the affected in-process material, or to approve and release the affected in-process material for use or distribution;

(2) Pending a documented review and material disposition decision, any in-process material that fails to meet any specification established in accordance with § 106.6(c)(1) shall be clearly identified as such and shall be controlled under a quarantine system designed to prevent its use in manufacturing or processing operations until completion of the documented review and material disposition decision;

(3) Any in-process material that has been reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use; and

(4) Any rejected in-process material shall be clearly identified as having been rejected for use in infant formula

and shall be controlled under a quarantine system designed to prevent its use in infant formula manufacturing or processing operations.

§ 106.55 Controls to prevent adulteration from microorganisms.

(a) A manufacturer of infant formula shall establish a system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

(b) A manufacturer of liquid infant formula shall comply, as appropriate, with the procedures specified in part 113 of this chapter for thermally processed low-acid foods packaged in hermetically sealed containers and part 114 of this chapter for acidified foods.

(c) A manufacturer of powdered infant formula shall test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standards in the table in paragraph (e) of this section.

(d) A manufacturer shall make and retain records, in accordance with § 106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms.

(e) A powdered infant formula that contains any microorganism that exceeds the M value listed for that microorganism in the table in paragraph (e) of this section shall be deemed adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)). The Food and Drug Administration will determine compliance with the M values listed below using the latest edition of the *Bacteriological Analytical Manual* (BAM) (*http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm*) (accessed April 8, 2013).

Microorganism	n[1]	Sample size	M value
Cronobacter spp.	30	10 g (grams)	[2]0.
Salmonella spp.	60	25 g	[2]0.

[1] Number of samples.
[2] None detected.

§ 106.60 Controls to prevent adulteration during packaging and labeling of infant formula.

(a) A manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, the correct use-by date, and the correct code established under § 106.80.

(b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.

(c) Packaging used to hold multiple containers of an infant formula product shall be labeled as follows:

(1) Where all containers are the same infant formula product and all bear the same code established under § 106.80, the packaging label shall include the product name, the name of the manufacturer, distributor, or shipper, and the code established under § 106.80.

(2) Where the containers are not the same infant formula product or do not all bear the same code established under § 106.80, the packaging label shall:

(i) Include the product name of each product, the name of the manufacturer, distributor, or shipper of each product, the code established under § 106.80 for each product, and a "use by" date that is no later than the "use by" date of the container exhibiting the closest "use by" date applied to satisfy the requirement of § 107.20(c) of this chapter; or

(ii) Include a unique identification number assigned by the packager, provided that the distributor of the package maintains a record linked to such unique number that identifies the product name of each product, the name of the manufacturer, distributor, or shipper of each product, the code established under § 106.80 for each product, and the "use by" date for each product applied to satisfy the requirement of § 107.20(c) of this chapter.

§ 106.70 Controls on the release of finished infant formula.

(a) A manufacturer shall control under a quarantine system designed to prevent use or distribution of each production aggregate of infant formula until it determines that the production aggregate meets all of the manufacturer's specifications, including those adopted to meet the standards of § 106.55 on microbiological contamination and of § 106.91(a) on quality control procedures, or until the documented review of the failure to meet any of the manufacturer's specifications finds that the failure does not result in, or could not lead to, adulteration of the product.

(b) Any production aggregate of infant formula that fails to meet any of the manufacturer's specifications shall be quarantined under a system designed to prevent its use in the manufacture of infant formula or its distribution until an individual qualified by education, training, or experience has conducted a documented review and has made and documented a material disposition decision to reject the infant formula; to reprocess or otherwise recondition the infant formula; or to approve and release the infant formula. Any production aggregate of infant formula that is reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use or distribution.

(c) Any rejected infant formula shall be clearly identified as having been rejected for use and shall be controlled under a quarantine system designed to prevent its release or distribution.

(d) A production aggregate of infant formula, including a reprocessed or reconditioned production aggregate, that does not meet the nutrient requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under sections 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) shall not be approved and released for distribution.

§ 106.80 Traceability.

Each production aggregate of infant formula shall be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used.

§ 106.90 Audits of current good manufacturing practice.

(a) A manufacturer of an infant formula, or an agent of such manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the current good manufacturing practice regulations in this subpart. Such audits shall be conducted at a frequency that is required to ensure compliance with such regulations.

(b) The audits required by paragraph (a) of this section shall be performed by an individual or a team of individuals who, as a result of education, training, or experience, is knowledgeable in all aspects of infant formula production and of the Agency's regulations concerning current good manufacturing practice that such individual or team is responsible for auditing. This individual or team of individuals shall have no direct responsibility for the matters that such individual or team is auditing and shall have no direct interest in the outcome of the audit.

Subpart C—Quality Control Procedures

§ 106.91 General quality control.

(a) During manufacture, a manufacturer shall test each production aggregate for nutrients as follows:

(1) Each nutrient premix used in the manufacture of an infant formula shall be tested for each nutrient (required under § 107.100 of this chapter or otherwise added by the manufacturer) that the manufacturer is relying on the premix to provide, to ensure that the premix is in compliance with the manufacturer's specifications;

(2) During the manufacturing process, after the addition of the premix, or at the final product stage but before distribution, each production aggregate of infant formula shall be tested for at least one indicator nutrient for each of the nutrient premixes used in the infant formula to confirm that the nutrients supplied by each of the premixes are present, in the proper concentration, in the production aggregate of infant formula.

(3) At the final product stage, before distribution of an infant formula, each production aggregate shall be tested for vitamins A, C, E, and thiamin.

(4) During the manufacturing process or at the final product stage, before distribution, each production aggregate shall be tested for all nutrients required to be included in such formula under § 107.100 of this chapter for which testing is not conducted for compliance with paragraphs (a)(1) or (a)(3) of this section and for any nutrient added by the manufacturer for which testing is not conducted for compliance with paragraph (a)(1) of this section.

(b) A manufacturer shall test each production aggregate of finished product for nutrients as follows:

(1) For an infant formula that is a new infant formula, § 106.3, the manufacturer shall collect, from each manufacturing site and at the final product stage, a representative sample of the first production aggregate of packaged, finished formula in each physical form (powder, ready-to-feed, or concentrate) and evaluate the levels of all nutrients required under § 107.100 of this chapter and all other nutrients added by the manufacturer. The manufacturer shall repeat such testing every 3 months thereafter throughout the shelf-life of the product.

(2) The manufacturer shall collect, from each manufacturing site and at the final product stage, a representative sample of each subsequent production aggregate of packaged, finished formula in each physical form (powder, ready-to-feed, or concentrate) and evaluate the levels of all nutrients required under § 107.100 and all other nutrients added by the manufacturer. The manufacturer shall repeat such testing at the midpoint and at the end of the shelf-life of the product.

(3) If the results of the testing required by paragraph (b)(1) of this section do not substantiate the shelf life of the infant formula, the manufacturer shall either repeat the testing required by such paragraph on a subsequently produced production aggregate to substantiate the shelf life of the infant formula or revise the shelf life label statement for such product so that such statement is substantiated by the stability testing results.

(4) If results of the testing required by paragraph (b)(2) of this section show that any required nutrient is not present in the production aggregate of infant formula at the level required by § 107.100 of this chapter or that any nutrient added by the manufacturer is not present at the level declared on the label of the production aggregate of infant formula, the manufacturer shall:

(i) Investigate the cause of such variance in the level of any required or added nutrient;

(ii) Evaluate the significance, if any, of the results for other production aggregates of the same formula that have been released for distribution;

(iii) Address, as appropriate, all production aggregates of formula released for distribution that are implicated by the testing results; and

(iv) Determine whether it is necessary to repeat the testing required by paragraph (b)(1) of this section.

(5) The testing required by paragraphs (b)(1) and (b)(2) of this section is not required to evaluate the level of minerals present in the infant formula.

(c) All quality control testing shall be conducted using appropriate, scientifically valid test methods.

(d) A manufacturer shall make and retain quality control records in accordance with § 106.100(e)(5)(i).

§ 106.92 Audits of quality control procedures.

(a) A manufacturer of an infant formula, or an agent of such a manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the requirements for quality control procedures that are necessary to ensure that an infant formula provides nutrients in accordance with section 412(b) and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b) and (i)) and is manufactured in a manner designed to prevent adulteration of the infant formula under section 412(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act. Such audits shall be conducted at a frequency that is required to ensure compliance with the requirements for quality control procedures.

(b) The audits required by paragraph (a) of this section shall be performed by an individual or a team of individuals who, as a result of education, training, or experience, is knowledgeable in all aspects of infant formula production and of the regulations concerning quality control procedures that such individual or team is responsible for auditing. This individual or team of individuals shall have no direct responsibility for the matters that such individual or team is auditing and shall have no direct interest in the outcome of the audit.

Subpart D—Conduct of Audits

§ 106.94 Audit plans and procedures.

(a) A manufacturer shall develop and follow a written audit plan that is available at the manufacturing facility for Food and Drug Administration inspection.

(b) The audit plan shall include audit procedures that set out the methods the manufacturer uses to determine whether the facility is operating in accordance with current good manufacturing practice, with the quality control procedures that are necessary to ensure that an infant formula provides nutrients in accordance with sections

412(b) and (i) of the Federal Food, Drug, and Cosmetic Act, and in a manner designed to prevent adulteration of the infant formula.

(c) The audit procedures shall include:

(1) An evaluation of the production and in-process control system established under § 106.6(b) by:

(i) Observing the production of infant formula and comparing the observed process to the written production and in-process control plan required under § 106.6(b);

(ii) Reviewing records of the monitoring of points, steps, or stages where control is deemed necessary to prevent adulteration; and

(iii) Reviewing records of how deviations from any specification at points, steps, or stages where control is deemed necessary to prevent adulteration were handled; and

(2) A review of a representative sample of all records maintained in accordance with § 106.100(e) and (f).

Subpart E—Quality Factors for Infant Formulas

§ 106.96 Requirements for quality factors for infant formulas.

The regulations set forth in this subpart define the minimum requirements for quality factors for infant formulas:

(a) An infant formula shall meet the quality factor of normal physical growth.

(b) A manufacturer of an infant formula that is not an eligible infant formula shall demonstrate that a formula supports normal physical growth in infants when fed as a sole source of nutrition by conducting, in accordance with good clinical practice, an adequate and well-controlled growth monitoring study of the infant formula that:

(1) Is no less than 15 weeks in duration, enrolling infants no more than 2 weeks old at time of entry into the study;

(2) Includes the collection and maintenance of data on formula intake and anthropometric measures of physical growth, including body weight, recumbent length, head circumference, average daily weight increment, and average daily recumbent length increment;

(3) Includes anthropometric measurements made at the beginning and end of the study, and at least four additional measurements made at intermediate time points with three of the six total measurements made within the first 4 weeks of the study and three measurements made at approximately 4-week intervals over the remaining 11 weeks of the study;

(4) Compares the anthropometric data for the test group to a concurrent control group or groups at each time point and compares the anthropometric data for each infant (body weight for age, body length for age, head circumference for age, and weight for length) in the test group and the control group to the 2009 CDC growth charts, which are incorporated by reference at § 106.160; and

(5) Compares the data on formula intake of the test group with a concurrent control group or groups and a scientifically appropriate reference.

(c) The Food and Drug Administration will exempt a manufacturer from the requirements of paragraph (b) of this section, if:

(1) The manufacturer requests an exemption and provides assurances, as required under § 106.121, that the changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging of an existing infant formula (e.g., changing from metal cans to plastic pouches); or

(2) The manufacturer requests an exemption and provides assurances, as required under § 106.121, which demonstrate that:

(i) An alternative method or study design that is based on sound scientific principles is available to show that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition;

(ii) The change made by the manufacturer to an existing formula does not affect the bioavailability of the formula, including the bioavailability of nutrients in such formula; or

(iii) The manufacturer markets a formulation in more than one form (e.g., liquid and powdered forms) and the quality factor requirements are met by the form of the formula that is processed using the method that has the greatest potential for adversely affecting nutrient content and bioavailability.

(d) A manufacturer of a new infant formula that is not an eligible infant formula shall, in accordance with § 106.100(p)(1), make and retain records demonstrating that the formula meets the quality factor of normal physical growth.

(e) An infant formula shall meet the quality factor of sufficient biological quality of protein.

(f) A manufacturer of an infant formula that is not an eligible infant formula shall demonstrate that a formula meets the quality factor of sufficient biological quality of protein by establishing the biological quality of the protein in the infant formula when fed as the sole source of nutrition using an appropriate modification of the Protein Efficiency Ratio (PER) rat bioassay described in the "Official Methods of Analysis of AOAC International," 18th ed., sections 45.3.04 and 45.3.05, "AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay," which is incorporated by reference at § 106.160. The PER rat bioassay shall be conducted on a formula and the results evaluated prior to the initiation of a growth monitoring study of the formula that is required under paragraph (b) of this section.

(g) The Food and Drug Administration will exempt a manufacturer from the requirements of paragraph (f) of this section, if:

(1) The manufacturer requests an exemption and provides assurances as required under § 106.121 that the changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging of an existing infant formula (e.g., changing from metal cans to plastic pouches); or

(2) The manufacturer requests an exemption and provides assurances, as required under § 106.121, that demonstrate that the change made by the manufacturer to an existing formula does not affect the bioavailability of the protein.

(h) A manufacturer of a new infant formula that is not an eligible infant formula shall, in accordance with § 106.100(q), make and retain records demonstrating that the formula meets the quality factor of sufficient biological quality of protein.

(i) The following provisions for requirements for quality factors apply only to an "eligible infant formula" as defined in § 106.3:

(1) An eligible infant formula that fulfills one or more of the following criteria meets the quality factor of normal physical growth:

(i) The scientific evidence on such infant formula meets the requirements of paragraph (b) of this section that apply to infant formula that is not an eligible infant formula;

(ii) The scientific evidence on such infant formula meets the following provisions:

(A) The evidence is an adequate and well-controlled growth study, conducted in accordance with good clinical practice, to determine whether an infant formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition;

(B) The growth study is no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study;

(C) The growth study collects from the study subjects data on anthropometric measures of physical growth, including body weight, recumbent length, head circumference, and average daily weight increment, and plots the data on the following charts from "Physical Growth: National Center for Health Statistics Percentiles" for body weight, body length, and head circumference, which are incorporated by reference at § 106.160:

(*1*) *Figure 1.* Length by age percentiles for girls aged birth–36 months (p. 609);

(*2*) *Figure 2.* Length by age percentiles for boys aged birth–36 months (p. 610);

(*3*) *Figure 3.* Weight by age percentiles for girls aged birth–36 months (p. 611);

(*4*) *Figure 4.* Weight by age percentiles for boys aged birth–36 months (p. 612);

(*5*) *Figure 5.* Head circumference by age percentiles for girls aged birth–36 months (p. 613);

(*6*) *Figure 6.* Weight by length percentiles for girls aged birth–36 months (p. 613);

(*7*) *Figure 7.* Head circumference by age percentiles for boys aged birth–36 months (p. 614); and

(*8*) *Figure 8.* Weight by length percentiles for boys aged birth–36 months (p. 614); and

(D) The growth study collects anthropometric measurements at the beginning of the growth study, at 2 weeks, at 4 weeks, at least monthly thereafter, and at the conclusion of the study; or

(iii) The scientific evidence on such infant formula otherwise demonstrates that such formula supports normal physical growth.

(2) An eligible infant formula that fulfills one or more of the following criteria meets the quality factor of sufficient biological quality of the protein:

(i) The scientific evidence on such infant formula meets the requirements of paragraph (f) of this section that apply to infant formula that is not an eligible infant formula;

(ii) The scientific evidence on such infant formula is a study that establishes the biological quality of the protein in an infant formula by demonstrating that the protein source supports adequate growth using the Protein Efficiency Ratio (PER) rat bioassay described in sections 45.3.04 and 45.3.05 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 16th ed., which are incorporated by reference at § 106.160; or

(iii) The scientific evidence on such infant formula otherwise demonstrates that the protein in such infant formula is of sufficient biological quality.

(3) The manufacturer of an eligible infant formula may, not later than November 12, 2015, submit a petition to the Food and Drug Administration under § 10.30 of this chapter that:

(i) Demonstrates that such formula fulfills one or more of the criteria in paragraph (i)(1) of this section; or

(ii) Demonstrates that such formula fulfills one or more of the criteria in paragraph (i)(2) of this section.

(4) A petition filed under paragraph (i)(3) of this section shall address only one infant formula formulation and shall contain all data and information relied upon by the manufacturer to demonstrate that such formulation fulfills one or more of the criteria in paragraph (i)(1) or in paragraph (i)(2) of this section. A manufacturer may combine petitions submitted under paragraphs (i)(3)(i) and (i)(3)(ii) of this section that relate to the same formulation.

(5) The manufacturer of each eligible infant formula shall make and retain, in accordance with § 106.100(p)(2), records to demonstrate that such formula supports normal physical growth in infants when fed as the sole source of nutrition and shall make and retain, in accordance with § 106.100(q)(2), records to demonstrate that that the protein in such infant formula is of sufficient biological quality. The records required by this paragraph shall include all relevant scientific data and information and a narrative explanation of why the data and information demonstrate that the formula supports normal physical growth and a narrative explanation of why the data and information demonstrate that the protein in such infant formula is of sufficient biological quality.

Subpart F—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a)).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(2)(C)).

(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:

(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manufacturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).

(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the Federal Food, Drug, and Cosmetic Act and § 107.100 of this chapter.

(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:

(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the Federal Food, Drug, and Cosmetic Act or § 107.100 of this chapter and any other nutrient listed in the certificate and guarantee;

(2) The weight of each nutrient added;

(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and

(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

(e) For each production aggregate of infant formula, a manufacturer shall prepare and maintain records that include complete information relating to the production and control of the production aggregate. These records shall include:

(1) The master manufacturing order. The master manufacturing order shall include:

(i) The significant steps in the production of the production aggregate and the date on which each significant step occurred;

(ii) For a manufacturing facility that has more than one set of equipment or more than one processing line, the identity of equipment and processing lines for which the manufacturer has identified points, steps, or stages in the production process where control is necessary to prevent adulteration;

(iii) The identity of each lot of ingredients, containers, and closures used in producing the production aggregate of formula;

(iv) The amount of each ingredient to be added to the production aggregate of

infant formula and a check (verification) that the correct amount was added; and

(v) A copy of each infant formula label used on a finished production aggregate of infant formula and the results of examinations conducted during the finishing operations to provide assurance that the containers and packages have the correct label.

(2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations.

(3) Documentation, in accordance with § 106.6(c), of the monitoring at any point, step, or stage in the manufacturer 's production process where control is deemed necessary to prevent adulteration. These records shall include:

(i) A list of the specifications established at each point, step, or stage in the production process where control is deemed necessary to prevent adulteration, in accordance with § 106.6(c)(1), including documentation of the scientific basis for each specification;

(ii) The actual values obtained during the monitoring operation, any deviations from established specifications, and any corrective actions taken; and

(iii) Identification of the person monitoring each point, step, or stage in the production process where control is deemed necessary to prevent adulteration.

(4) The conclusions and followup, along with the identity of the individual qualified by education, training, or experience who investigated:

(i) Any deviation from the master manufacturing order and any corrective actions taken;

(ii) A finding that a production aggregate or any of its ingredients failed to meet the infant formula manufacturer's specifications; and

(iii) A failure to meet any specification at any point, step, or stage in the production process where control is deemed necessary to prevent adulteration.

(5) The results of all testing performed on the production aggregate of infant formula, including testing on the in-process production aggregate, at the final product stage, and on finished product throughout the shelf life of the product. The results recorded shall include:

(i) The results of all quality control testing conducted in accordance with § 106.91(a) and (b) to verify that each nutrient required by § 107.100 of this chapter is present in each production aggregate of infant formula at the level required by § 107.100 of this chapter, and that all other nutrients added by the manufacturer are present at the appropriate level. The record of the results of the quality control testing shall include:

(A) A summary document identifying the stages of the manufacturing process at which the nutrient analysis for each required nutrient is conducted as required under § 106.91(a); and

(B) A summary document on the stability testing program conducted under § 106.91(b), including the nutrients tested and the frequency of nutrient testing throughout the shelf life of the product.

(ii) For powdered infant formula, the results of any testing conducted in accordance with § 106.55(c) to verify compliance with the microbiological quality standards in § 106.55(e).

(f) A manufacturer shall make and retain all records described in subparts B and C of this part, including:

(1) Records, in accordance with § 106.20(f)(4), of the frequency and results of testing of the water used in the production of infant formula;

(2) Records, in accordance with § 106.30(d), of accuracy checks of instruments and controls. A certification of accuracy of any known reference standard used and a history of recertification shall be maintained. At a minimum, such records shall specify the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test. If calibration of an instrument shows that a specification at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and any actions that need to be taken with respect to that product, shall be made.

(3) Records, in accordance with § 106.30(e)(3)(iii).

(4) Records, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the lot number of each production aggregate of infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed.

(5) Records, in accordance with § 106.35(c), on all mechanical and electronic equipment used in the production or quality control of infant formula. These records shall include:

(i) A list of all systems used with a description of the computer files and the defined capabilities and inherent limitations of each system;

(ii) A copy of all software used;

(iii) Records that document installation, calibration, testing or validation, and maintenance of the systems used;

(iv) A list of all persons authorized to create or modify software;

(v) Records that document modifications to software, including the identity of the person who modified the software;

(vi) Records that document retesting or revalidation of modified systems; and

(vii) A backup file of data entered into a computer or related system. The backup file shall consist of a hard copy or alternative system, such as duplicate electronic records, tapes, or microfilm, designed to ensure that backup data are exact and complete, and that they are secure from alteration, inadvertent erasures, or loss.

(6) Records, in accordance with § 106.40(g), on ingredients, containers, and closures used in the manufacture of infant formula. These records shall include:

(i) The identity and quantity of each lot of ingredients, containers, and closures;

(ii) The name of the supplier;

(iii) The supplier's lot numbers;

(iv) The name and location of the manufacturer of the ingredient, container, or closure, if different from the supplier;

(v) The date of receipt;

(vi) The receiving code as specified; and

(vii) The results of any test or examination (including retesting and reexamination) performed on the ingredients, containers, or closures and the conclusions derived there from and the disposition of all ingredients, containers, or closures.

(7) A full description of the methodology used to test powdered infant formula to verify compliance with the microbiological quality standards of § 106.55(c) and the methodology used to do quality control testing, in accordance with § 106.91(a).

(g) A manufacturer shall maintain all records pertaining to distribution of the infant formula, including records that show that formula produced for export only is exported. Such records shall include all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of part 107 of this chapter.

(h) The manufacturer shall maintain all records pertaining to the microbiological quality and purity of raw materials and finished powdered infant formula.

(i) [Reserved]

(j) The manufacturer shall make and retain records pertaining to regularly scheduled audits, including the audit plans and procedures, the findings of the audit, and a listing of any changes made in response to these findings. The manufacturer shall make readily available for authorized inspection the audit plans and procedures and a statement of assurance that the regularly scheduled audits are being conducted. The findings of the audit and any changes made in response to these findings shall be maintained for the time period required under paragraph (n) of this section, but need not be made available to the Food and Drug Administration.

(k) The manufacturer shall maintain procedures describing how all written and oral complaints regarding infant formula will be handled. The manufacturer shall follow these procedures and shall include in them provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health.

(1) For purposes of this section, every manufacturer shall interpret a "complaint" as any communication that contains any allegation, written or oral, expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a hazard to health and about appearance, taste, odor, and quality. Correspondence about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health shall not, for compliance purposes, be considered a complaint and therefore need not be made available to a Food and Drug Administration investigator.

(2) When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. Where such an investigation is conducted, the manufacturer shall include in its file on the complaint the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall include in the record the reason that an investigation was found to be unnecessary and the name of the responsible person making that determination.

(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the Agency as required in § 106.150.

(4) The manufacturer shall maintain in designated files all records pertaining to the complaints it receives. The manufacturer shall separate the files into two classes:

(i) Those complaints that allege that the infant became ill from consuming the product or required treatment by a physician or health care provider and

(ii) Those complaints that may involve a possible existence of a hazard to health but do not refer to an infant becoming ill or the need for treatment by physician or a health care provider.

(5) The manufacturer shall include in a complaint file the following information concerning the complaint:

(i) The name of the infant formula;

(ii) The batch number;

(iii) The name of complainant;

(iv) A copy of the complaint or a memo of the telephone conversation or meeting and all correspondence with the complainant;

(v) By reference or copy, all the associated manufacturing records and complaint investigation records needed to evaluate the complaint. When copies of such records are not maintained in the complaint file, they must be available within 24 hours when requested by a Food and Drug Administration official.

(vi) All actions taken to followup on the complaint; and

(vii) All findings and evaluations of the complaint.

(6) The manufacturer should maintain the files regarding infant formula complaints at the establishment where the infant formula was manufactured, processed, or packed. When the manufacturer wishes to maintain all consumer complaints for the entire firm at one location other than at the facility where an infant formula was manufactured, processed, or packed, the manufacturer may do so as long as all records required by this section are available within 24 hours of request for inspection at that facility. However, all records of consumer complaints, including summaries, any reports, and any files, maintained at the manufacturing facility or at any other facility shall be made available to investigators for review and copying upon request.

(l) The manufacturer shall make readily available for authorized inspection all records required under this part or copies of such records. Records shall be available at any reasonable time at the establishment where the activities described in such records occurred. (Infant formula complaint files may be maintained at one facility, as provided in paragraph (k)(6) of this section, if all required records are readily available at that facility.) These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by electronic means shall be considered as meeting the requirements of this paragraph.

(m) A manufacturer shall maintain all records required under part 106 in a manner that ensures that both the manufacturer and the Food and Drug Administration can be provided with immediate access to such records. The manufacturer may maintain the records required under part 106 as original records, as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records, or as electronic records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available. All electronic records maintained under part 106 shall comply with part 11 of this chapter.

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, and 113 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

(o) The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any batch of infant formula.

(p) A manufacturer shall make and retain records that demonstrate that the formula meets the quality factor of normal physical growth.

(1) For an infant formula that is not an eligible infant formula, in accordance with § 106.96(d), these records shall include:

(i) Records demonstrating compliance with the requirements in § 106.96(b), including records made in compliance with § 106.121; or

(ii) Records demonstrating satisfaction of an applicable exemption under § 106.96(c), including records made in compliance with § 106.121.

(2) For an eligible infant formula, in accordance with § 106.96(i)(5), these records shall include records demonstrating that the formula fulfills one or more of the criteria listed in § 106.96(i)(1).

(q) A manufacturer shall make and retain records that demonstrate that a formula meets the quality factor of sufficient biological quality of protein.

(1) For an infant formula that is not an eligible infant formula, in accordance with § 106.96(h), these records shall include:

(i) Records demonstrating compliance with the requirements in § 106.96(f), including records made in compliance with § 106.121; or

(ii) Records demonstrating satisfaction of an applicable exemption under § 106.96(g), including records made in compliance with § 106.121.

(2) For an eligible infant formula, in accordance with § 106.96(i)(5), these records shall include records demonstrating that the formula fulfills one or more of the criteria listed in § 106.96(i)(2).

(r) The failure to comply with the records requirements in this section applicable to the quality factors shall render the formula adulterated under section 412(a)(2) of the Federal Food, Drug, and Cosmetic Act. The failure to comply with the records requirements in this section applicable to the good manufacturing practices and quality control procedures, including distribution and audit records requirements, with respect to an infant formula shall render the formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act. A failure to retain or make available records applicable to the quality factor requirements, quality control procedures, or current good manufacturing practices requirements in compliance with paragraph (l), (m), or (n) of this section with respect to a formula shall render the formula adulterated under section 412(a)(2) or (a)(3) of the Federal Food, Drug, and Cosmetic Act, as applicable.

Subpart G—Registration, Submission, and Notification Requirements

§ 106.110 New infant formula registration.

(a) Before a new infant formula may be introduced or delivered for introduction into interstate commerce, including a new infant formula for export only, the manufacturer of the formula shall register with the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS–850), 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

(b) The new infant formula registration shall include:

(1) The name of the new infant formula;

(2) The name of the manufacturer;

(3) The street address of the place of business of the manufacturer; and

(4) The name and street address of each establishment at which the manufacturer intends to manufacture such new infant formula.

§ 106.120 New infant formula submission.

(a) At least 90 days before a new infant formula is introduced or delivered for introduction into interstate commerce, a manufacturer shall submit notice of its intent to do so to the Food and Drug Administration at the address given in § 106.110(a). An original and two paper copies of such notice of intent shall be submitted, unless the notice is submitted in conformance with part 11 of this chapter, in which case a single copy shall be sufficient.

(b) The new infant formula submission shall include:

(1) The name and description of the physical form (e.g., powder, ready-to feed, or concentrate) of the infant formula;

(2) An explanation of why the formula is a new infant formula;

(3) The quantitative formulation of each form of the infant formula that is the subject of the notice in units per volume or units per weight for liquid formulas, specified either as sold or as fed, and units per dry weight for powdered formulas, and the weight of powder to be reconstituted with a specified volume of water, and, when applicable, a description of any reformulation of the infant formula, including a listing of each new or changed ingredient and a discussion of the effect of such changes on the nutrient levels in the formulation;

(4) A description, when applicable, of any change in processing of the infant formula. Such description shall identify the specific change in processing, including side-by-side, detailed schematic diagrams comparing the new processing to the previous processing and processing times and temperatures;

(5) Assurance that the infant formula will not be marketed unless the formula meets the requirements for quality factors of section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)(1)) and the nutrient content requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act.

(i) Assurance that the formula meets the requirements for quality factors, which are set forth in § 106.96, shall be provided by a submission that complies with § 106.121;

(ii) Assurance that the formula complies with the nutrient content requirements, which are set forth in § 107.100 of this chapter, shall be provided by a statement that the formula will not be marketed unless it meets the nutrient requirements of § 107.100 of this chapter, as demonstrated by testing required under subpart C of this part; and

(6) Assurance that the processing of the infant formula complies with section 412(b)(2) of the Federal Food, Drug, and Cosmetic Act. Such assurance shall include:

(i) A statement that the formula will be produced in accordance with subparts B and C of this part; and

(ii) The basis on which each ingredient meets the requirements of § 106.40(a), e.g. that it is an approved food additive, that it is authorized by a prior sanction, or that it is generally recognized as safe (GRAS) for its intended use. Any claim that an ingredient is GRAS shall be supported by a citation to the Agency's regulations or by an explanation, including a list of published studies and a copy of those publications, for why, based on the published studies, there is general recognition of the safety of the use of the ingredient in infant formula.

(c) For a new infant formula for export only, a manufacturer may submit, in lieu of the information required under paragraphs (b)(5) and (b)(6) of this section, a statement certifying that the infant formula meets the specifications of the foreign purchaser, the infant formula does not conflict with the laws of the country to which it is intended for export, the infant formula is labeled on the outside of the shipping package to indicate that it is intended for export only, and the infant formula will not be sold or offered for sale in domestic commerce. Such manufacturer shall also submit a statement certifying that it has adequate controls in place to ensure that such formula is actually exported.

(d) The submission will not constitute notice under section 412 of the Federal Food, Drug, and Cosmetic Act unless it complies fully with paragraph (b) of this section, as applicable, and the information that it contains is set forth in a manner that is readily understandable. The Agency will notify the manufacturer if the notice is not complete because it does not meet the requirements in section 412(c) and (d) of the Federal Food, Drug, and Cosmetic Act.

(e) If a new infant formula submission contains all the information required by

paragraph (b) of this section, as applicable, the Food and Drug Administration will acknowledge its receipt and notify the manufacturer of the date of receipt. The date that the Agency receives a new infant formula submission that is complete is the filing date for such submission. The manufacturer shall not market the new infant formula before the date that is 90 days after the filing date. If the information in the submission does not provide the assurances required under section 412(d)(1) of the Federal Food, Drug, and Cosmetic Act and the regulations of this chapter, the Food and Drug Administration will so notify the manufacturer before the expiration of the 90th day.

(f) If the manufacturer provides additional information in support of a new infant formula submission, the Agency will determine whether the additional information is a substantive amendment to the new infant formula submission. If the Agency determines that the new submission is a substantive amendment, the Food and Drug Administration will assign the new infant formula submission a new filing date. The Food and Drug Administration will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by the Food and Drug Administration of the information that constitutes the substantive amendment to the new infant formula submission.

(g) Submissions relating to exempt infant formulas are subject to the provisions of § 107.50 of this chapter.

§ 106.121 Quality factor assurances for infant formulas.

To provide assurance that an infant formula meets the requirements for quality factors set forth in § 106.96, the manufacturer shall submit the following data and information:

(a) Unless the manufacturer of a new infant formula can claim an exemption under § 106.96(c)(1) or (c)(2), the following assurances shall be provided to ensure that the requirements of § 106.96(a) and (b) have been met:

(1) An explanation, in narrative form, setting forth how requirements for quality factors in § 106.96(b) have been met;

(2) Records that contain the information required by § 106.96(b) to be collected during the study for each infant enrolled in the study. The records shall be identified by subject number, age, feeding group, gender, and study day of collection.

(3) Data, which shall include:

(i) Statistical evaluation for all measurements, including group means, group standard deviations, and measures of statistical significance for all measurements for each feeding group at the beginning of the study and at every point where measurements were made throughout the study, and

(ii) Calculations of the statistical power of the study before study initiation and at study completion.

(4) A report on attrition and on all occurrences of adverse events during the study, which shall include:

(i) Identification of the infant by subject number and feeding group and a complete description of the adverse event, including comparisons of the frequency and nature of occurrence in each feeding group and information on the health of the infant during the course of the study, including the occurrence and duration of any illness;

(ii) A clinical assessment by a health care provider of the infant's health during each suspected adverse event; and

(iii) A list of all subjects who did not complete the study, including the subject number and the reason that each subject did not complete the study.

(b) If the manufacturer is requesting an exemption from the growth monitoring study requirements under § 106.96(c)(1), the manufacturer shall include a detailed description of the change made by the manufacturer to an existing infant formula and an explanation of why the change made by the manufacturer to an existing infant formula satisfies the criteria of § 106.96(c)(1).

(c) If the manufacturer is requesting an exemption under § 106.96(c)(2)(i), the manufacturer shall include a detailed description of the alternative method or alternative study design, an explanation of why the method or study design is based on sound scientific principles, and data that demonstrate that the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition.

(d) If the manufacturer is requesting an exemption under § 106.96(c)(2)(ii), the manufacturer shall include a detailed description of the change and an explanation of why the change made by the manufacturer to an existing infant formula does not the affect the bioavailability of the formula, including the bioavailability of the nutrients in such formula.

(e) If the manufacturer is requesting an exemption under § 106.96(c)(2)(iii), the manufacturer shall include a detailed description of the two formulations and an explanation of why the quality factor requirement of normal physical growth is met by the form of the formula that is processed using the method that has the greatest potential for adversely affecting nutrient content and bioavailability.

(f) Unless the manufacturer of a new infant formula is requesting an exemption under § 106.96(g), the results of the Protein Efficiency Ratio bioassay shall be provided in accordance with § 106.96(f).

(g) If the manufacturer is requesting an exemption under § 106.96(g)(1), the manufacturer shall include a detailed description of the change made by the manufacturer to an existing infant formula and an explanation of why the change made by the manufacturer to an existing infant formula satisfies the criteria listed in § 106.96(g)(1).

(h) If the manufacturer is requesting an exemption under § 106.96(g)(2), the manufacturer shall include a detailed description of the change and an explanation of why the change made by the manufacturer to an existing infant formula does not affect the bioavailability of the protein.

(i) A statement certifying that the manufacturer has collected and considered all information and data concerning the ability of the infant formula to meet the requirements for quality factors and that the manufacturer is not aware of any information or data that would show that the formula does not meet the requirements for quality factors.

§ 106.130 Verification submission.

(a) A manufacturer shall, after the first production and before the introduction into interstate commerce of a new infant formula (except for a new infant formula that is for export only for which a submission is received in compliance with § 106.120(c)), verify in a written submission to the Food and Drug Administration at the address given in § 106.110(a) that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated.

(b) The verification submission shall include the following information:

(1) The name of the new infant formula; the filing date for the new infant formula submission, in accordance with § 106.120, for the subject formula; and the identification number assigned by the Agency to the new infant formula submission:

(2) A statement that the infant formula to be introduced into interstate commerce is the same as the infant formula that was the subject of the new infant formula notification and for which the manufacturer provided

assurances in accordance with the requirements of § 106.120;

(3) A summary of test results of the level of each nutrient required by § 107.100 of this chapter and any nutrient added by the manufacturer in the formula, presented in units per 100 kilocalories at the final product stage.

(4) A certification that the manufacturer has established current good manufacturing practices, including quality control procedures and in-process controls, and testing required by current good manufacturing practice, designed to prevent adulteration of this formula in accordance with subparts B and C of this part.

(c) The submission shall not constitute written verification under section 412(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)(2)) when any data prescribed in paragraph (b) of this section are lacking or are not set forth so as to be readily understood. In such circumstances, the Agency will notify the manufacturer that the notice is not adequate.

§ 106.140 Submission concerning a change in infant formula that may adulterate the product.

(a) When a manufacturer makes a change in the formulation or processing of the formula that may affect whether the formula is adulterated under section 412(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)), the manufacturer shall, before the first processing of such formula, make a submission to the Food and Drug Administration at the address given in § 106.110(a). An original and two copies shall be submitted.

(b) The submission shall include:

(1) The name and physical form of the infant formula (i.e., powder, ready-to-feed, or concentrate);

(2)(i) An explanation of why the change in formulation or processing may affect whether the formula is adulterated; and

(ii) What steps will be taken to ensure that, before the formula is introduced into interstate commerce, the formula will not be adulterated; and

(3) A statement that the submission complies with § 106.120(b)(3), (b)(4), (b)(5), and (b)(6). When appropriate, a statement to the effect that the information required by § 106.120(b)(3), (b)(4), (b)(5), or (b)(6) has been provided to the Agency previously and has not been affected by the changes that are the subject of the current submission, together with the identification number assigned by the Agency to the relevant infant formula submission, may be provided in lieu of such statement.

(c) The submission shall not constitute notice under section 412 of the Federal Food, Drug, and Cosmetic Act unless it complies fully with paragraph (b) of this section, and the information that it contains is set forth in a manner that is readily understandable. The Agency will notify the manufacturer if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the Federal Food, Drug, and Cosmetic Act.

§ 106.150 Notification of an adulterated or misbranded infant formula.

(a) A manufacturer shall promptly notify the Food and Drug Administration in accordance with paragraph (b) of this section when the manufacturer has knowledge (that is, actual knowledge that the manufacturer had, or the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d(i)) or by regulations issued under section 412(i)(2); or

(2) May be otherwise adulterated or misbranded.

(b) The notification made according to paragraph (a) of this section shall be made by telephone, to the Director of the appropriate Food and Drug Administration district office. After normal business hours (8 a.m. to 4:30 p.m.), the Food and Drug Administration's emergency number, 1–866–300–4374 shall be used. The manufacturer shall promptly send written confirmation of the notification to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement (HFS–605), Recall Coordinator, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office.

§ 106.160 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Food and Drug Administration must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Food and Drug Administration library at 10903 New Hampshire Ave., Building 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, and is available from the sources listed below. This material is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) 3–A Sanitary Standards, Inc., 6888 Elm St., Suite 2D, McLean, VA 22101–3829, 703–790–0295, and may be ordered online at *http://www.3-a.org/*:

(1) 3–A Sanitary Standards, No. 609–03: A Method of Producing Culinary Steam, adopted November 21, 2004, into § 106.20(h).

(2) [Reserved]

(c) American Society for Nutrition, 9650 Rockville Pike, Bethesda, MD 20814–3998, 301–634–7279, *http://www.nutrition.org*:

(1) *Physical growth: National Center for Health Statistics percentiles,* Hamill, P.V.V., T.A. Drizd, C.L. Johnson, R.B. Reed, A.F. Roche, and W.M. Moore, *American Journal of Clinical Nutrition,* vol. 32, pp. 607–614, dated March 1979, into § 106.96(i)(1)(ii)(c).

(2) [Reserved]

(d) AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, 301–924–7078:

(1) Official Methods of Analysis of AOAC International, 16th ed., dated 1995, into § 106.96(i)(2)(ii):

(i) Section 45.3.04, AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay, and

(ii) Section 45.3.05, AOAC Official Method 982.30 Protein Efficiency Ratio Calculation Method.

(2) Official Methods of Analysis of AOAC International, 18th ed., dated 2005, into § 106.96(f):

(i) Section 45.3.04, AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay, and

(ii) Section 45.3.05, AOAC Official Method 982.30 Protein Efficiency Ratio Calculation Method.

(e) Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333, 1–800–232–4636, *http://www.cdc.gov/growthcharts/who_charts.htm.*

(1) *Birth to 24 months:* Boys Head circumference-for-age and Weight-for-length percentiles, dated November 1, 2009, into § 106.96(b)(4).

(2) *Birth to 24 months:* Boys Length-for-age and Weight-for-age percentiles, dated November 1, 2009, into § 106.96(b)(4).

(3) *Birth to 24 months:* Girls Head circumference-for-age and Weight-for-length percentiles, dated November 1, 2009, into § 106.96(b)(4).

(4) *Birth to 24 months:* Girls Length-for-age and Weight-for-age percentiles, dated November 1, 2009, into § 106.96(b)(4).

PART 107—INFANT FORMULA

■ 2. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

■ 3. Add § 107.1 to subpart A to read as follows:

§ 107.1 Status and applicability of the regulations in part 107.

(a) The criteria in subpart B of this part describe the labeling requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 343). Failure to comply with any regulation in subpart B of this part will render an infant formula misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria in subpart C of this part describe the terms and conditions for the exemption of an infant formula from the requirements of section 412(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a), (b), and (c)). Failure to comply with any regulations in subpart C of this part will result in withdrawal of the exemption given under section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act.

(c) Subpart D of this part contains the nutrient requirements for infant formula under section 412(i) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart D of this part will render an infant formula adulterated under section 412(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(d) An exempt infant formula is subject to the provisions of § 107.50 and other applicable Food and Drug Administration food regulations.

■ 4. Amend § 107.3 by revising the definition of "Manufacturer" to read as follows:

§ 107.3 Definitions.

* * * * *

Manufacturer. A person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution. The term "manufacturer" does not include a person who prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.

* * * * *

■ 5. Amend § 107.10 by revising paragraph (a) introductory text, paragraph (a)(2) introductory text, and paragraph (b)(5) to read as follows:

§ 107.10 Nutrient information.

(a) The labeling of infant formulas, as defined in section 201(z) of the Federal Food, Drug, and Cosmetic Act, shall bear in the order given, in the units specified, and in tabular format, the following information regarding the product as prepared in accordance with label directions for infant consumption:

* * * * *

(2) A statement of the amount, supplied by 100 kilocalories, of each of the following nutrients and of any other nutrient added by the manufacturer:

* * * * *

(b) * * *

(5) Any additional vitamin may be declared at the bottom of the vitamin list and any additional minerals may be declared between iodine and sodium, provided that any additionally declared nutrient:

(i) Has been identified as essential by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or has been identified as essential by the Food and Drug Administration through a **Federal Register** publication; and

(ii) Is provided at a level considered in these publications as having biological significance, when these levels are known.

■ 6. Amend § 107.50 by revising paragraph (e) to read as follows:

§ 107.50 Terms and conditions.

* * * * *

(e) *Notification requirements.* (1) Information required by paragraphs (b) and (c) of this section shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(2) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the Federal Food, Drug, and Cosmetic Act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the Food and Drug Administration Emergency Call Center at 866–300–4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

■ 7. Revise § 107.240 to read as follows:

§ 107.240 Notification requirements.

(a) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(b) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate FDA district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(1) Number of consignees notified of the recall and date and method of notification, including recalls required by § 107.200, information about the notice provided for retail display, and the request for its display.

(2) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at each consignee at the time the communication was received.

(3) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(4) Number and results of effectiveness checks that were made.

(5) Estimated timeframes for completion of the recall.

(c) *Status reports.* The recalling firm shall submit to the appropriate FDA district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the

recalling firm to carry out the recall since the last report and the results of these steps.

■ 8. Amend § 107.250 by revising the introductory text to read as follows:

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate FDA district office for transmittal to the Recall Coordinator, Division of Enforcement (HFS–605), Office of Compliance, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or by email to *CFSAN.RECALL@fda.hhs.gov*, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The Agency will respond within 15 days of receipt by the Division of Enforcement of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the Agency that the recall has been terminated. The Agency will send such notification, unless the Agency has information from FDA's own audits or from other sources demonstrating that the recall has not been effective. The Agency may conclude that a recall has not been effective if:

* * * * *

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02148 Filed 2–6–14; 8:45 am]

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FEDERAL REGISTER

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Part V

The President

Memorandum of January 31, 2014—Certification Concerning U.S. Participation in the United Nations Multidimensional Integrated Stabilization Mission in Mali Consistent With Section 2005 of the American Servicemembers' Protection Act

Federal Register
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Title 3—

The President

Memorandum of January 31, 2014

Certification Concerning U.S. Participation in the United Nations Multidimensional Integrated Stabilization Mission in Mali Consistent With Section 2005 of the American Servicemembers' Protection Act

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, and consistent with section 2005 of the American Servicemembers' Protection Act of 2002 (22 U.S.C. 7424), concerning the participation of members of the Armed Forces of the United States in certain United Nations peacekeeping and peace enforcement operations, I hereby certify that members of the U.S. Armed Forces participating in the United Nations Multidimensional Integrated Stabilization Mission in Mali are without risk of criminal prosecution or other assertion of jurisdiction by the International Criminal Court (ICC) because the Republic of Mali has entered into an agreement in accordance with Article 98 of the Rome Statute preventing the ICC from proceeding against members of the Armed Forces of the United States present in that country.

You are authorized and directed to publish this determination in the *Federal Register*.

THE WHITE HOUSE,
Washington, January 31, 2014

[FR Doc. 2014–03014
Filed 2–7–14; 11:15 am]
Billing code 4710–10

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